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(71) Applicant: UNIVERSITY OF IOWA RESEARCH FOUNDATION [US/US]; 112 N. Capitol Street, Iowa City, Iowa 52242 (US).

(72) Inventor: HOWARD, Matthew A.; c/o University of Iowa Research Foundation, 112 N. Capitol Street, Iowa City, Iowa 52242 (US).

(74) Agent: HARTUNG, Kirk, M. et al.; McKEE, VOORHEES & SEASE, P.L.C., 801 Grand Avenue, Suite 3200, Des Moines, Iowa 50309-2721 (US).

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(54) Title: RAPID MATCHING PROCESS FOR CRANIOPLASTY PLATES AND TEMPLATE

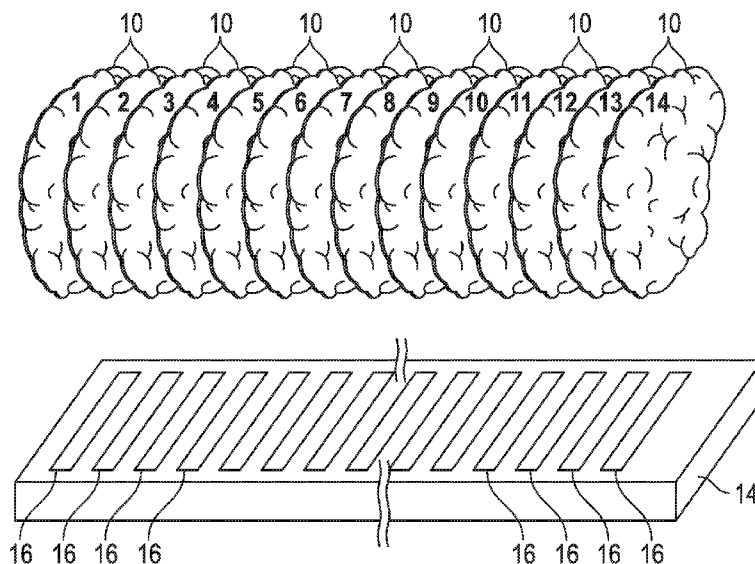


FIG. 3

(57) Abstract: A method is provided for matching a cranioplasty plate and template to a patient's skull in conjunction with an emergency or non-elective craniectomy surgery. A kit containing a plurality of sizes and shapes of cranioplasty plates and plate templates is provided, so that the medical professional or technician can select the plate and template which best matches the patient's skull dimensions based on imaging of the skull. The kit and selection process eliminate the need and time required for manufacture of a custom cranioplasty plate.



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**TITLE: RAPID MATCHING PROCESS FOR CRANIOPLASTY PLATES  
AND TEMPLATE**

**CROSS-REFERENCE TO RELATED APPLICATION**

5 This application claims priority under 35 U.S.C. § 119 to provisional application  
Serial No. 62/329,659, filed April 29, 2016, herein incorporated by reference in its entirety.

**BACKGROUND OF THE INVENTIONS**

10 A craniectomy is a medical surgical procedure commonly performed to  
manage intractable brain swelling, often caused by trauma or stroke. When a patient is  
managed using a standard craniectomy procedure, two surgeries are normally required.  
First, a craniotomy is performed, wherein a section of the skull is removed and then the  
skin or scalp is closed over the skull opening. The craniectomy allows for the brain tissue  
to expand through the opening to reduce intracranial pressure. After the brain swelling has  
15 receded, which may take several weeks or months, a second cranioplasty operation is  
required to replace the saved native bone material, or alternatively, to implant a prosthetic  
skull piece, such as a thin titanium skull plate. This second operation restores a solid  
covering over the skull opening or defect.

The removal of the skull section during the craniectomy procedure allows the brain  
20 tissue to expand without restriction by the skull. Without the skull protection, the brain is  
vulnerable under the skin until swelling reduces in the following weeks or months, and the  
cranioplasty surgery takes place to repair the skull defect. During the time interval  
between the craniectomy and the cranioplasty procedures, the patient normally wears a  
helmet to protect the brain. The cranioplasty surgery increases the high costs associated  
25 with caring for these injured patients. The cranioplasty procedure also increases the risk of  
further injury to the patient, due to the requirement to manipulate scalp and brain tissue  
during the cranioplasty procedures. These risks include intracranial hemorrhage and  
seizures, infection, and wound breakdown. Also, prior to the cranioplasty operation,  
patients often experience headaches and some develop neurological deficits due to brain  
30 distortion and abnormal compartmental pressure gradients related to the presence of a  
craniectomy defect.

Applicant's pending patent applications Serial No. 15/080,647 and 62/338,120 (both of which are incorporated herein by reference in their entirety) discloses a cranioplasty plate which replaces the conventional prior art plate used in current decompressive craniectomy procedures. As described in this co-pending application, the cranioplasty plate is placed over the skull defect after a bone flap has been removed, and has features that accommodate acute brain swelling and which enable the cranial plate to later be moved into an acceptable final position substantially flush with the skull surface after the brain swelling has abated, without the requirement for a second cranioplasty procedure.

For a cranioplasty procedure to be successful the implanted cranioplasty plate must have a size and shape that fits the patient's skull well. When a cranioplasty surgical procedure is planned in advance, a custom cranial plate can be manufactured to properly fit the patient's skull. Such custom plates are produced using a CT scan of the patient, with the CT scan data being sent to a manufacturer. An image processing algorithm is used to define the dimensions of the removed or missing bone flap for the patient. Then, a computer-aided manufacturing machine can create the custom cranial plate using the patient's imaged data. The plate is then shipped to the hospital prior to the scheduled craniectomy implantation surgery.

In a clinical situation where a craniectomy procedure will be performed and it is desirable to place a moveable cranioplasty plate over the skull defect, there is insufficient time to fabricate a custom cranioplasty plate. That is because many craniectomy procedures are performed as emergency operations, such as in the clinical setting of an acute stroke or traumatic brain injury. In such circumstances, the surgery may occur immediately or shortly after the CT scan, such as within one hour, which precludes the use of a patient-specific sized, custom made cranioplasty plate.

Therefore, there is a need for a method and means for rapidly matching an existing cranioplasty plate that most closely approximates the relevant dimensions of the skull of the patient undergoing an emergency craniectomy operation.

Accordingly, a primary objective of the present invention is the provision of a method for matching a cranioplasty plate selected from a kit of multiple plates to fit a patient's skull.

Another objective of the present invention is the provision of a method for matching a cranial plate template from a kit of different sized and shaped templates, to the patient's skull.

Another objective of the present invention is a provision of a method of quickly  
5 matching cranioplasty templates and plates to a patient's skull utilizing imaging data of the patient's skull.

A further objective of the present invention is the provision of a method to quickly and easily provide a properly fit cranioplasty plate for a patient.

Still another objective of the present invention is the provision of a kit of  
10 cranioplasty plates and templates for use in emergency combined craniectomy-cranioplasty procedures.

Another objective of the present invention is the provision of a process which allows for selection of an appropriate cranioplasty plate from a collection of plates done virtually over the internet by a technician remote from the operating room.

A further objective of the present invention is the provision of a collection of  
15 different sized and shaped cranioplasty plates held in spaced apart upright positions by a slotted base, with indicia on each plate to facilitate quick and easy selection of the appropriate plate for a patient based upon on imaging of the patient's skull.

Yet another objective of the present invention is the provision of a set of  
20 cranioplasty plates and a set of cranioplasty templates, both having varying sizes and shapes, and in which corresponding pairs of plates and templates having identical indicia for proper matching of a selected template and a selected plate.

A further objective of the present invention is the provision of a process for  
25 simplifying emergency or non-elective combined craniectomy-cranioplasty operations which quickly, easily and safely matches a cranioplasty plate to a patient's skull opening.

These and other objectives will become apparent from the following description of the invention.

#### **SUMMARY OF THE INVENTION**

30 A method is provided for matching a cranioplasty plate to the skull opening of a patient who has had a craniectomy, particularly in an emergency or a non-elective clinical setting. The method involves the collection or creation of a kit having a plurality of

different sized and shaped cranioplasty plates. Imaging data of the patient's skull is provided to a technician or other medical personnel. Then, one of the cranioplasty plates from the kit or collection is selected which most closely matches skull dimensions obtained from the patient's imaging data. The selection or matching step may be done from a  
5 location remote from the operating room, such as over the internet using email or other communication tools. The kit includes a comprehensive range of plates which may be used for different patients having skulls of different sizes and shapes. The kit may also include a plurality of bone flap templates, each having different sizes and shapes. The cranioplasty plates and the cranial plate templates have indicia, such as numbering, to quickly match  
10 pairs of templates and cranioplasty plates, in accordance with the results of the imaging data analysis. For quick and easy selection, the plates and templates are stored in a sterilized environment, such as in a stand or base having slots to hold the plates and templates in spaced apart, upright orientations.

#### 15 **BRIEF DESCRIPTION OF THE DRAWINGS**

Figure 1 is a flow chart showing one embodiment of the cranioplasty template matching process of the present invention.

Figure 2 is sketch showing an example of a kit having different sized and shaped cranioplasty templates, according to the present invention.

20 Figure 3 is a sketch showing an exploded view of a kit, with a base and multiple plates and/or templates, in accordance with the present invention.

#### **DESCRIPTION OF THE INVENTION**

To overcome the problem of insufficient time to manufacture a custom cranioplasty  
25 plate, even where fabrication capabilities are available in the hospital (such as rapid prototyping machines), the present invention provides a range of cranioplasty plates and templates of various sizes and shapes in a kit stored on-site, in or near the operating room, so that an appropriately sized template and plate can be selected from the kit at the operating room supply facility and used with a craniectomy patient. In a preferred  
30 embodiment, the kit will contain a first set of numbered cranioplasty plates 10 (Figure 3), and a second set of numbered templates 12 (Figure 3) which do not have the functionality of the plates but which match the plates 10 in size and shape. The templates 12 are used to

confirm the proper plate size to implant, and to trace around so as to outline the dimensions of the bone flap that will be removed from the patient's skull.

Preferably, each kit includes at least one base or stand 14 having a plurality of slots 16 which hold the plates 10 and templates 12 in spaced apart, substantially vertical or upright positions. The slots 16 can be formed in the base 14, as shown in Figure 3, or can be formed by upstanding fingers or dividers 18, as shown in Figure 2.

In one embodiment, all the templates 12 and plates 10 can be stored upright in one base or stand 14. In an alternative embodiment, separate bases or stands 14 can be provided for the plates 10 and templates 12, and/or for the left and right hemisphere of the skull, to segregate the left and right plates, and the left and right templates. A cover (not shown) may be provided on the base to enclose the plates and templates, and to maintain sterility of the plates and templates.

To create the kit of cranioplasty plates 10 and templates 12, a study or survey can be conducted to determine the range of skull plate sizes and shapes that are appropriate for patients undergoing decompressive craniectomy operations. For example, 100 patients who have undergone such surgery can be sampled so as to ascertain a comprehensive range of "off the shelf" plate sizes/shapes which would collectively provide an acceptable "fit" for all possible craniectomy patients. For example, the kit can include 12-15 different sizes with left and right hemisphere plates. Every hospital which performs such craniectomy surgical procedures will have the kit containing the full size/shape range of sterilized plates ready for implantation.

The plates 10 and templates 12 have indicia, such as numbers, as shown at the top of the templates in Figure 2 and the top of the plates in Figure 3, for ease of selection. The indicia can be located anywhere on the templates and plates that allows for easy reading while the plates and templates are stored in the slots of the base.

In a preferred embodiment shown in Figure 1, the process for selecting the properly sized plate from the kit should be efficient and effective. The plate/template selection can be made by the surgeon prior to implantation. Alternatively, the selection process can utilize telemedicine and image processing technologies. Since all trauma surgery hospitals have electronic medical record (EMR) systems 20 which store digital imaging data 22, when a patient who will require a craniectomy has a CT scan 24, the imaging data 22 is placed in the EMR system 20 for access via the internet 26 to care providers 28 and cranial

plate companies 30 located anywhere. Thus, a virtual cranial plate fitting can be conducted, as follows:

1. The surgeon reviews the patient's CT scan and other clinical relevant data, and decides whether to perform a decompressive craniectomy procedure. If such an emergency procedure is required, the operating room staff is notified and the procedure is scheduled.
2. A trained member of the staff sends an email (preferably with secured encryption) to create a patient medical record number (MRN), and indicate whether a left or right sided hemicraniectomy procedure is planned.
3. In a standardized, HIPAA compliant manner, a trained representative downloads the patient's CT scan data, and then creates a surface rendering of the patient's skull. A virtual bone flap template scaled to the patient's skull is overlaid on the image using a standard imaging algorithm.
4. The representative then uses the same algorithm to determine or select the cranioplasty plate size from the kit of plates, which conforms best to the size and shape of the patient's skull.
5. This "best fit" information is then sent to the operating room staff, preferably by secure email, which then conveys the information to the surgeon who uses the information for selection of the template 12 and the cranioplasty plate 10, in an efficient and effective manner. This process eliminates the time-consuming trial and error empiric fitting process that would be required otherwise in attempting to select and match the proper template and plate to the patient's skull.

All of these steps may take place quickly, for example, within one hour following the determination that the craniectomy surgery is necessary. With the kit of the present invention, the surgery can proceed quickly and with a properly sized template 12 and cranioplasty plate 10 for each individual patient, without the need for a custom sized plate that would not be possible to manufacture under these clinical time constraints.

Figure 1 shows the process according to the present invention, for the templates contained in the kit. Once the kits are created, they can be maintained on site at the hospital. As templates 12 and plates 10 are removed from the kit, the kit should be replenished to maintain a full set of the ranges of different sized  
5 and shaped templates and plates.

The kit of cranioplasty plates 10 and templates 12 includes a container or case for enclosing and storing the plates and templates. Alternatively, the plates and templates can be housed in separate containers. The container or case should be maintained in a sterile condition. Alternatively, the plates and templates can  
10 be sterilized after removal from the case and before use on the patient.

The invention has been shown and described above with the preferred embodiments, and it is understood that many modifications, substitutions, and additions may be made which are within the intended spirit and scope of the invention. From the foregoing, it can be seen that the present invention accomplishes at least all of its stated  
15 objectives.

**What is Claim is:**

1. A method for matching a cranioplasty plate to a patient's skull comprising:  
creating a kit of cranioplasty plates, with each plate having a different size or shape from  
5 the other plates in the kit;  
selecting one of the plates from the kit for use with the patient, wherein the selected plate  
provides a best fit match to the patient's skull.
2. The method of claim 1 further comprising creating a kit of cranial plate  
10 templates, with each template having a different size or shape from other templates in the  
kit.
3. The method of claim 2 wherein the templates correspond to the plates in the  
kit.
- 15 4. The method of claim 1 wherein the plate selection is made using imaging  
data of the patient's skull.
5. The method of claim 1 further comprising surveying cranioplasty patients to  
20 determine a comprehensive range of plates to be included in the kit.
6. The method of claim 1 further comprising sterilizing the plates before  
inclusion in the kit.
- 25 7. A kit for cranioplasty surgery, comprising:  
a plurality of cranioplasty plates;  
each of the plates having different sizes and shapes; and  
the plates including identifying indicia.
- 30 8. The kit of claim 7 further comprising a plurality of cranial templates, each  
template having different sizes and shapes and identifying indicia.

9. The kit of claim 7 further comprising a sterilized container for the plates.
10. The kit of claim 7 further comprising a stand with slots to individually support the plates.
- 5 11. The kit of claim 10 wherein the slots space the plates apart from one another.
12. The kit of claim 10 wherein the slots hold the plates in a vertical orientation.
- 10 13. The kit of claim 7 wherein a base to store the plates in spaced out, substantially vertical positions.
14. A process for non-elective cranioplasty plate implantation on a patient, comprising:
- 15 providing a plurality of different size, cranioplasty plates;  
providing imaging data of a patient's skull;  
selecting one of the cranioplasty plates which most closely matches the imaging data for the patient.
- 20 15. The process of claim 14 as none of the cranioplasty plates are custom fit.
16. The process of claim 14 wherein the plates are sterilized.
- 25 17. The process of claim 14 wherein the plates have different shapes.
18. The process of claim 14 further comprising providing a plurality of different sized cranial plate templates which correspond to the cranioplasty plates.
- 30 19. The process of claim 18 further comprising numbering the plates and templates, with corresponding plates and templates having the same number.

20. The process of claim 14 wherein the plates include left and right hemisphere versions.

21. The process of claim 14 wherein the selection step is performed remotely at  
5 a location separate from location of the patient.

22. The process of claim 14 wherein the selection step is done virtually over the Internet by a technician apart from operating room personnel.

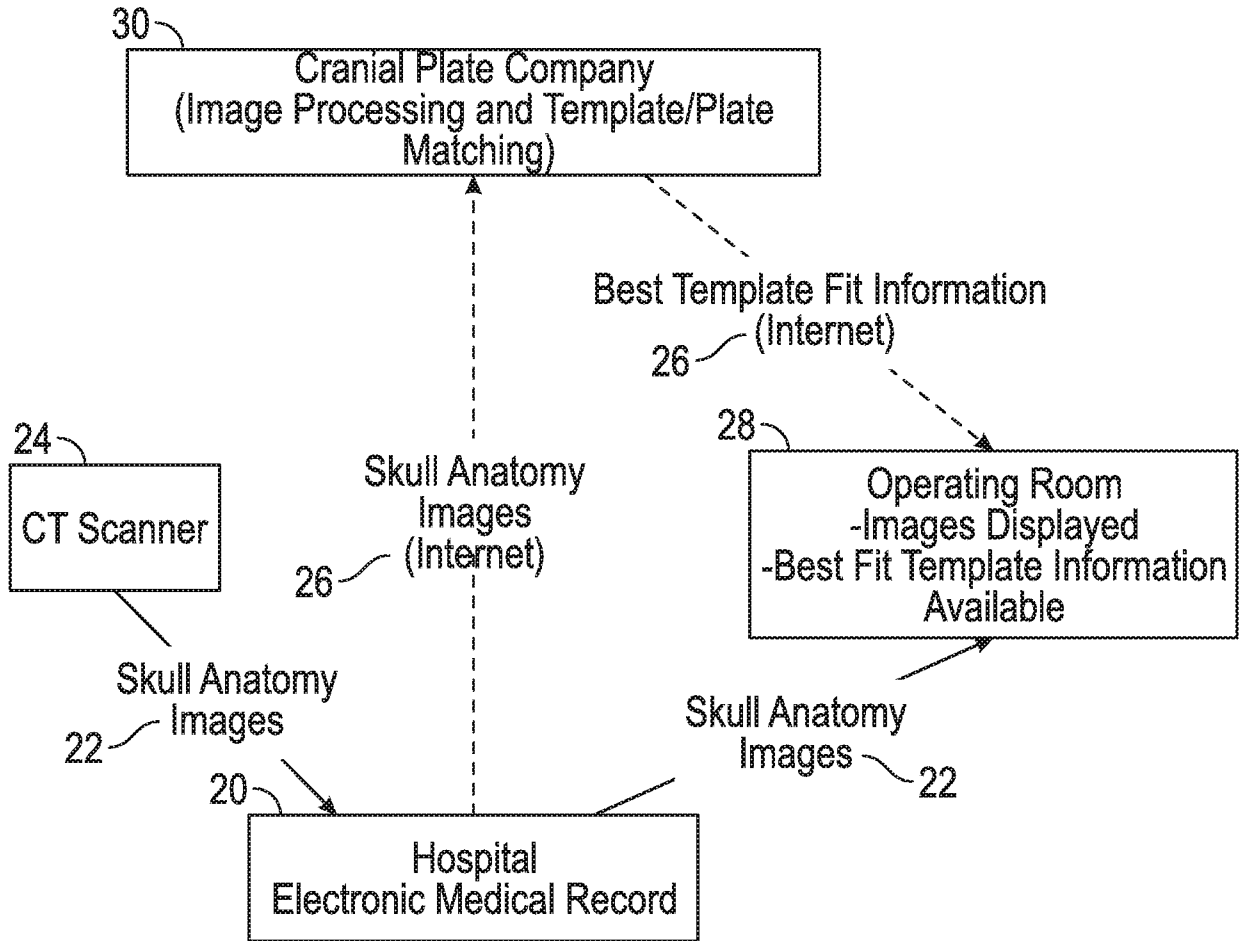


FIG. 1

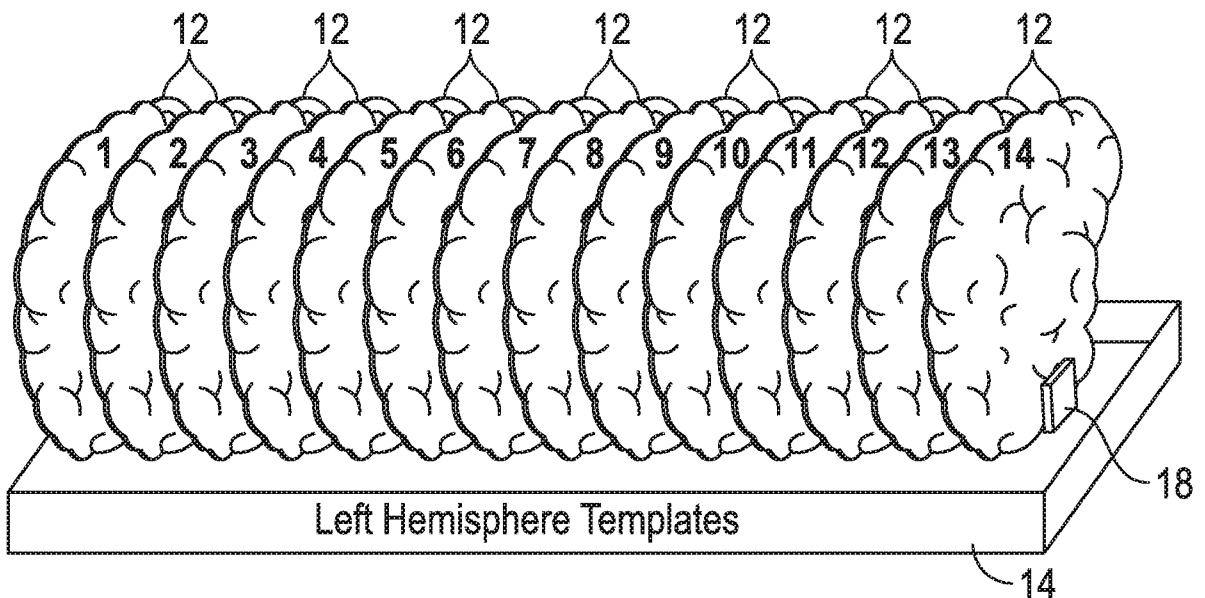


FIG. 2

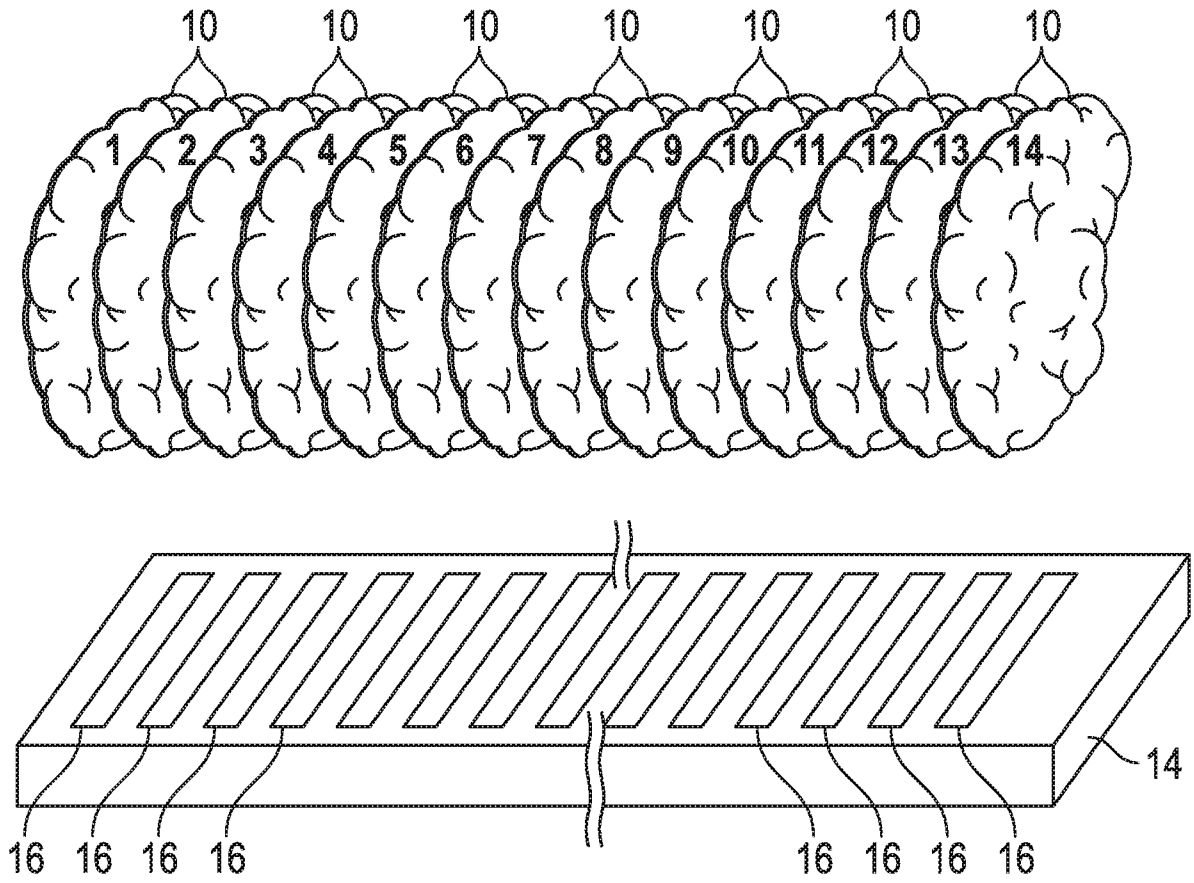


FIG. 3

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2017/030368

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 17/56; A61B 17/58; A61B 17/68; A61B 17/80; A61B 17/88; A61F 2/28 (2017.01)

CPC - A61B 17/8061; A61B 2017/568; A61F 2/2875; A61F 2/3094; A61F 2/30942; A61F 2002/2878; A61F 2002/2882; A61F 2002/2885; A61F 2002/2889; A61F 2002/30948; A61F 2002/3095; A61F 2002/3096; A61F 2240/004 (2017.05)

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

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History document

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

USPC - 606/71; 606/280; 606/281; 606/286; 623/901; 623/17.19 (keyword delimited)

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

See Search History document

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,690,631 A (DUNCAN et al) 25 November 1997 (25.11.1997) entire document	1, 5, 6
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Y		2-4, 7-22
Y	US 2015/0265448 A1 (HABERL et al) 24 September 2015 (24.09.2015) entire document	2, 3, 8, 18, 19
Y	US 2012/0203289 A1 (BEERENS et al) 09 August 2012 (09.08.2012) entire document	4, 7-22
Y	US 2012/0138495 A1 (BETTENHAUSEN et al) 07 June 2012 (07.06.2012) entire document	10-13

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

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P.O. Box 1450, Alexandria, VA 22313-1450

Facsimile No. 571-273-8300

Authorized officer

Blaine R. Copenheaver

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