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(54) **Title:** VIRTUAL STENT DEPLOYMENT

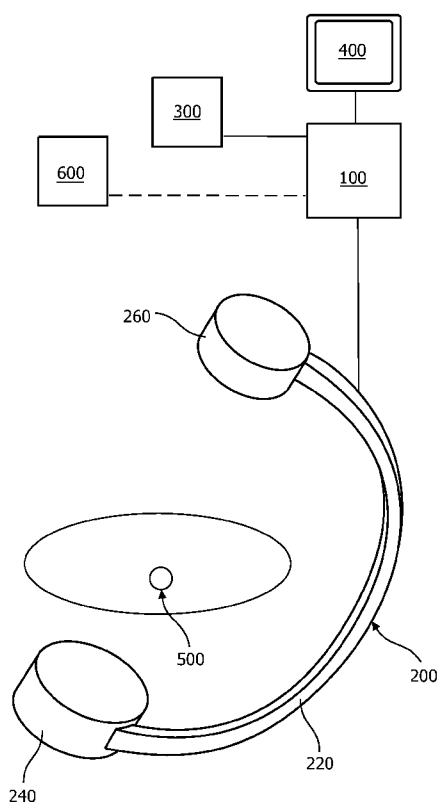


FIG. 2

(57) **Abstract:** It is proposed by the invention to simulate a deployment of an actual stent at a current position of said stent, wherein the simulation is based on geometrical information extracted from image data received from an imaging device, wherein the image data represent an anatomical structure and the stent relative to the anatomical structure, and on an identified position of the stent. The simulated stent may be visualized together with an X-ray image of the anatomical structure.



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VIRTUAL STENT DEPLOYMENT

FIELD OF THE INVENTION

The invention relates to the field of stents. Particularly, the invention relates to a computer program and a system for supporting a positioning of a stent in an anatomical structure.

5 BACKGROUND OF THE INVENTION

Heart valve diseases are among the most prominent causes for heart failure. 3 to 4 million people will require heart valve replacement at some point in their live. Heart valves can be replaced during an open surgery. But open heart surgery is very invasive with long recovery time, it is very expensive, and the patient group is limited as for some patients the risk of anesthesia and open surgery is too high.

10 Minimally invasive valve replacement in the cathlab promises a less invasive treatment at much lower cost for more patients. To achieve minimally invasive replacement of the aortic valve or the pulmonary valve, the artificial valve is mounted in a stent which is positioned using a catheter under x-ray guidance . This is a challenging procedure which still bears a not negligible risk for the patient.

15 US 7,650,179 B2 discloses a computerized workflow method for stent planning and conducting procedure, wherein characteristics of a lesion to be stented are determined from a 3D planning image of the region and selection of an actual stent for stenting the lesion is made with computer-assisted analysis of the lesion based on the characteristics. A virtual stent is electronically generated based on the actual stent, and, using the virtual stent, a best position for the actual stent, for effectively stenting the lesion, is determined. A real time 2D image of the lesion-containing region is displayed during the stenting procedure, with the virtual stent included therein at the aformentioned best position. A physician manually guides the actual stent relative to the lesion during the stenting procedure until the position of the actual stent, as seen in the displayed real time 2D image, coincides with the virtual stent in that image.

SUMMARY OF THE INVENTION

It is an object of the invention to provide a computer program and a system for supporting a positioning of a stent in an anatomical structure, especially a positioning of a stent including valves, in the region of the aortic valves.

5 This is achieved by the subject-matter of each of the independent claims. Further embodiments are described in the respective dependent claims.

The exact positioning of a stent for aortic valve replacement is crucial, since, if the stent is placed too low, the mitral valves might be disturbed; if it is placed too high, the flow into the coronaries might be impeded; and if it is placed in an
10 inappropriate angle, the positioning might not be stable. Additionally, bad positioning can lead to embolization and paravulvular insufficiency.

The exact positioning of the stent is therefore very difficult and once the stent has been fully opened, the positioning cannot be adjusted during the minimally invasive procedure but only during open heart surgery.

15 Therefore it is proposed by the invention to simulate a deployment of an actual stent at a current position of said stent, wherein the simulation is based on geometrical information extracted from image data representing an anatomical structure, and on the identified position of the stent. The anatomical structure may include the natural aortic valves.

20 The image data may be received directly from an image device, for example a live 2D C-arm based X-ray device. This image data may represent both the anatomical structure and the stent relative to the anatomical structure. On the other hand, there may be provided image data representing the anatomical structure separately from the stent relative to the anatomical structure.

25 The image data may otherwise be received from a data base at which previously recorded image data are stored, wherein the image data of the data base may be for example data from 3D computer tomography, 3D ultrasound or a rotational X-ray scan. In this case, the image data should be registered with for example live 2D images, providing for a link between the geometrical information extracted from the image data
30 of the data base, and the identified position of the stent relative to the currently imaged anatomical structure.

By means of the invention, an answer is given to the question of a clinician: "If I would open the stent starting from the current position, how would it be positioned after deployment?"

Such a simulation is performed by a computer program according to the invention, comprising corresponding sets of instructions.

According to an embodiment of the invention, the stent may be tracked, so that the identification of the position of the stent relative to the anatomical structure is performed automatically. Such a tracking may be realized by an identification of for example a marker at the stent visible in an image, by an electro-magnetic tracking independent from a visualization of the stent or by methods for measuring the shape of a catheter.

Furthermore, the stent may be identified, so that the simulation may additionally be based on at least one parameter of the stent, which may be a deployed length, a deployed diameter, an elasticity and an deployed shape.

Further, the anatomical structure together with the simulated stent as deployed at the identified position, may be visualized.

A corresponding computer program is preferably loaded into a work memory of a data processor. The data processor or processing unit is thus equipped to carry out the method of the invention. Further, the invention relates to a computer-readable medium such as a CD-ROM at which the computer program may be stored. However, the computer program may also be presented over a network like the World Wide Web and can be downloaded into the working memory of the data processor from such a network.

According to another embodiment of the invention, a system for supporting a positioning of a stent in an anatomical structure, comprises an imaging device capable of generating image data representing an anatomical structure and a stent relative to the anatomical structure, processing means capable of extracting geometrical information of the anatomical structure, capable of identifying a position of the stent relative to the anatomical structure, and capable of simulating a deployment of the stent at the identified position, and a monitor for visualizing the anatomical structure and at the identified position the simulated stent.

It is noted, that the processing means may be realized by only one processor performing all the steps of the invention, or by a group or plurality of processors, for example a system processor for processing the image data, a separate processor specialized on a simulation of a deployment of a stent, and a further processor for controlling a monitor for visualizing the result.

The system may further comprise a computer program as mentioned above, wherein the computer program may be executable on the processing means.

The system may further comprise input means for manually identifying the stent and/or the position of the stent. Such input device may be for example a
5 computer keyboard, a computer mouse or a touch screen.

Furthermore, the system may comprise storage means providing for a data base including parameter data of the stent. It will be understood, that such storage means may also be provided in a network to which the system according to the invention may be connected and information related to the stent, i.e. different types of
10 stents and parameter thereof, may be received over that network.

It has to be noted that embodiments of the invention are described with reference to different subject-matters. In particular, some embodiments are described with reference to method type claims (computer program) whereas other embodiments are described with reference to apparatus type claims (system). However, a person
15 skilled in the art will gather from the above and the following description that unless other notified in addition to any combination of features belonging to one type of subject-matter also any combination between features relating to different subject-matters is considered to be disclosed with this application.

The aspects defined above and further aspects, features and advantages of
20 the present invention can also be derived from the examples of the embodiments to be described hereinafter and are explained with reference to examples of embodiments also shown in the figures, but to which the invention is not limited.

BRIEF DESCRIPTION OF THE DRAWINGS

- 25 Fig. 1 shows a flow chart of steps performed in accordance with the invention.
- Fig. 2 shows a schematical illustration of a system according to the invention.
- Fig. 3 shows an exemplary segmentation of an anatomical structure.
- 30 Fig. 4 shows exemplary images of a stent implantation.
- Fig. 5 shows a visualization of a virtually deployed stent.

DETAILED DESCRIPTION OF THE EMBODIMENTS

The key question during a stent implantation is: If the stent would be opened starting from a current position, how would it be positioned after deployment.

The idea of this intervention is to simulate the deployment of the stent taking into account the patient anatomy, the stent geometry and the current stent position. To achieve this, the patient anatomy is determined from a 3D imaging modality and the position and orientation of the unopened or not yet fully opened stent is determined from the live x-ray image. Then, the opening of the stent is simulated taking into account all available information.

The results of the virtual stent deployment are visualized and certain risk structures could be highlighted. The visualization can also be overlaid onto the live x-ray stream.

The flow-chart in Fig. 1 illustrates the principle of the steps performed in accordance with the invention. It will be understood that the steps described, are major steps, wherein these major steps might be differentiated or divided into several sub-steps. Furthermore, there might be also sub-steps between these major steps. Therefore, a sub-step is only mentioned if this step may be important for the understanding of the principles of the method according to the invention.

In step S1, a stent is determined, which means that a stent to be implanted is selected and identified, out of a plurality of stent potentially usable. After selecting a stent suitable for a patient, the parameter of the stent, for example the length, the diameter and the elasticity or the shape may be identified for an un-deployed and a deployed state.

In step S2, image data are received. For example, an X-ray device may provide image data of a region including the heart of a patient, wherein artificial heart valves should be implanted as supplement of the native aortic valves. Furthermore, the image data may be received from a data base.

In step S3, geometrical information are extracted from the image data, that is, the 3D contour of the aortic bulbus and the aortic valves are determined based on the received image data.

In step S4, a current position of the introduced but not yet deployed actual stent is identified. This may be done by for example clicking with a mouse at the position at which the un-deployed stent is visible in an X-ray image. Otherwise, the

stent may be automatically tracked, so that the current position of the stent is automatically determined. In this case, any kind of input may trigger the following step.

In step S5, a deployment of the actual stent is simulated resulting in a virtual visualization of the deployed stent.

5 In step S6, this virtually deployed stent is shown onto an X-ray image at the site at which the actual stent would have been located if actually deployed.

Fig. 2 shows an exemplary embodiment of a system according to the invention. Substantially, necessary for performing the steps according to the invention, a processing unit 100 together with a monitor 400 is part of the system.

10 The exemplary imaging device 200 includes an X-ray source 240, and an X-ray detector 260, wherein these two devices are mounted on a C-arm 220. It will be understood that the system in accordance with the invention may also comprise a non-invasive imaging modality like a computer tomography device, a magnetic resonance device, or an ultrasound device as imaging device instead of or additional to the shown
15 C-arm based X-ray device.

Furthermore, the system in fig. 2 includes an input device 300, by means of which for example a manual selection of a utilized stent or a manual identification of the current position of the stent may be performed. Also shown is a connection (as dotted line) to a data base 600, located for example in a network.

20 Finally, there is shown a region of interest 500. Within said region, for example a heart of a patient may be located which is subject of an implantation of an artificial heart valve. Examples of images from an imaging device 200, can be seen in figures 3 and 4.

In fig. 3, examples for a segmentation are shown. In a preparatory step
25 the 3D geometry of the aortic bulbus, the coronary ostia, the aortic valve, the left ventricular outflow tract and the mitral valve are determined. This can be achieved using a model-based segmentation, as disclosed in O. Ecabert, J. Peters, H. Schramm, C. Lorenz, J. von Berg, M. J. Walker, M. Vembar, M. E. Olszewski, K. Subramanyan, G. Lavi, and J. Weese: "Automatic Model-Based Segmentation of the Heart in CT
30 images," IEEE Transactions on Medical Imaging, Vol. 27(9), p. 1189-1201, 2008. The geometry can be determined from pre-interventional images, like CT or MRI, or from peri-interventional images, like 3D ultrasound or rotational angiography.

In order to give meaningful results, the simulation of the stent deployment must be able to take the current position of stent and catheter into account.

This can be achieved by tracking the stent and the catheter in the live x-ray image during the intervention.

Example x-ray images from a minimally invasive valve replacement are shown in Figure 4.

5 Before the deployment (upper left image of figure 4), contrast agent is injected into the aorta. These images can be utilized to register the x-ray projection images to the 3D patient anatomy which was obtained earlier. Then, the stent is deployed, i.e. released from the catheter (upper right and lower left images of figure 4). After deployment (lower right image in figure 4), the function of the stent may be
10 controlled by injecting a contrast agent, as shown.

 When the initial position of the stent with respect to the patient anatomy is known, it is possible to simulate the stent deployment. The patient geometry and the stent geometry may be represented by a mesh. Then, the forces on the stent and the resulting displacements can be computed. Depending on the type of the stent, it is either
15 deployed by removing a sheath from the stent or by expanding a balloon inside the stent. This has to be taken into account when modeling the forces on the stent.

 The stent may be represented by a deformable simplex mesh, it is initialized using the centerline of the vessel, and it is deformed by internal and external forces onto the mesh taking into account some stent shape constraints. Such a stent
20 representation may be gathered from I. Larrabide, A. F. Frangi: "Virtual stent deployment with simplex meshes," 5th European Congress on Computational Methods in Applied Sciences and Engineering, 2008.

 The results of virtual stent deployment can be visualized together with for example a geometric model of the patient so that the quality of the positioning can
25 be assessed by the clinician. An example of such a visualization is shown in Figure 5.

 Alternatively, the results can be overlaid onto the x-ray image. Additionally, the result can be used to automatically assess the quality of the positioning of the stent.

 As soon as a clinician reaches a position at which a simulation of the
30 deployment of the stent results in a acceptable positioning of the deployed stent, the clinician may actually deploy the stent and thus position the actual stent as simulated.

 While the invention has been illustrated and described in detail in the drawings and afore-going description, such illustrations and descriptions are to be

considered illustrative or exemplary and not restrictive, the invention is not limited to the disclosed embodiments.

Other variations to the disclosed embodiments can be understood and effected by those skilled in the art in practising the claimed invention, from a study of the drawings, the disclosure and the appended claims. In the claims, the word
5 “comprising” does not exclude other elements or steps, and the indefinite article “a” or “an” does not exclude a plurality. A single processor or other unit may fulfil the functions of several items recited in the claims.

The mere fact that certain measures are recited and mutually different
10 dependent claims does not indicate that a combination of these measures can not be used to advantage. The computer program may be stored/distributed on a suitable medium such as an optical storage medium or a solid-state medium supplied together with or as a part of another hardware, but may also be distributed in other forms, such as
15 via the Internet or other wired or wireless telecommunication systems. Any reference signs in the claims should not be construed as limiting the scope.

LIST OF REFERENCE SIGNS

	100	processing means
	200	imaging device
5	220	C-arm
	240	X-ray source
	260	X-ray detector
	300	input device
	400	monitor
10	500	region of interest
	510	heart valve
	520	actual stent
	530	introduction device
	540	virtual stent
15	600	data base

CLAIMS:

1. A computer program for executing on a system for supporting a positioning of a stent in an anatomical structure, the computer program including:
sets of instructions for receiving image data from an imaging device
5 (200), the image data representing the anatomical structure and the actual stent (520),
sets of instructions for receiving geometrical information of the anatomical structure,
sets of instructions for identifying a current position of the actual stent
(520) relative to the anatomical structure,
10 sets of instructions for simulating a deployment of the stent (540),
wherein the simulation is based on the received geometrical information and on the identified position of the actual stent (520).

2. The computer program of claim 1, wherein the received geometrical
15 information is extracted from the image data from the imaging device (200) or from an image data base (600), the image data representing the anatomical structure.

3. The computer program of claim 1, further comprising set of
instructions for registering the image data from the imaging device (200) to the
20 geometrical information of the anatomical structure.

4. The computer program of claim 1, further comprising sets of
instructions for tracking the actual stent (520), so that the identification of the position
of the stent relative to the anatomical structure is performed automatically.
25

5. The computer program of claim 1, further comprising sets of
instructions for identifying the actual stent (520), wherein the simulation is further
based on a parameter of the identified actual stent.

6. The computer program of claim 5, wherein the parameter is at least
30 one parameter out of the group consisting of deployed length, deployed diameter,
elasticity and deployed shape.

7. The computer program of claim 1, further comprising sets of instructions for visualizing the anatomical structure together with the simulated stent (540) as deployed at the identified position.

5

8. A system for supporting a positioning of a stent in an anatomical structure, the system comprising:

an imaging device (200) capable of generating image data representing an anatomical structure and an actual stent (520) relative to the anatomical structure,

10

processing means (100) capable of extracting geometrical information of the anatomical structure, and capable of identifying a position of the actual stent relative to the anatomical structure,

wherein the processing means is further capable of simulating a deployment of the stent (540) at the identified position, and

15

a monitor (400) for visualizing the anatomical structure and at the identified position the simulated stent (540).

9. The system of claim 8, further comprising a computer program according to any one of claims 1 to 7, wherein the computer program is executable on the processing means.

20

10. The system of claim 8, further comprising input means (300) for manually identifying the actual stent (520) and/or the position of the actual stent.

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11. The system of claim 8, further comprising a data base (600) including image data of the anatomical structure and parameter data of the actual stent (520).

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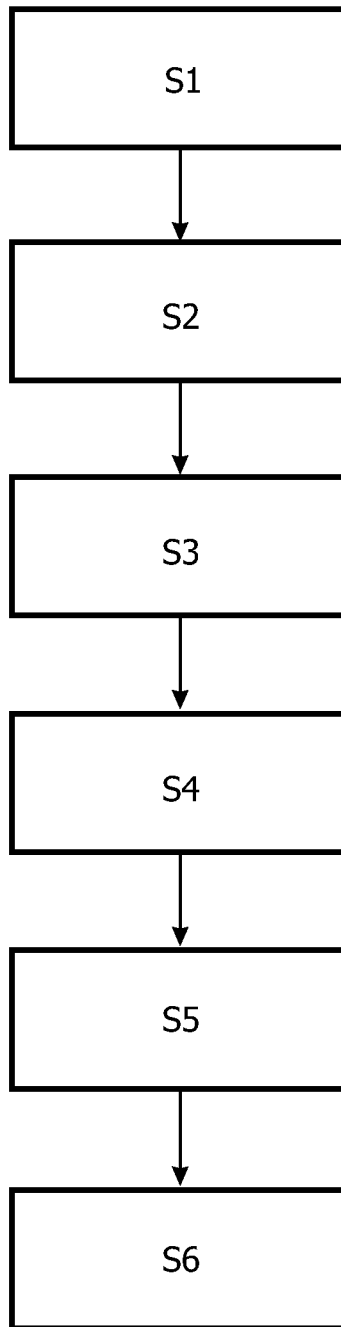


FIG. 1

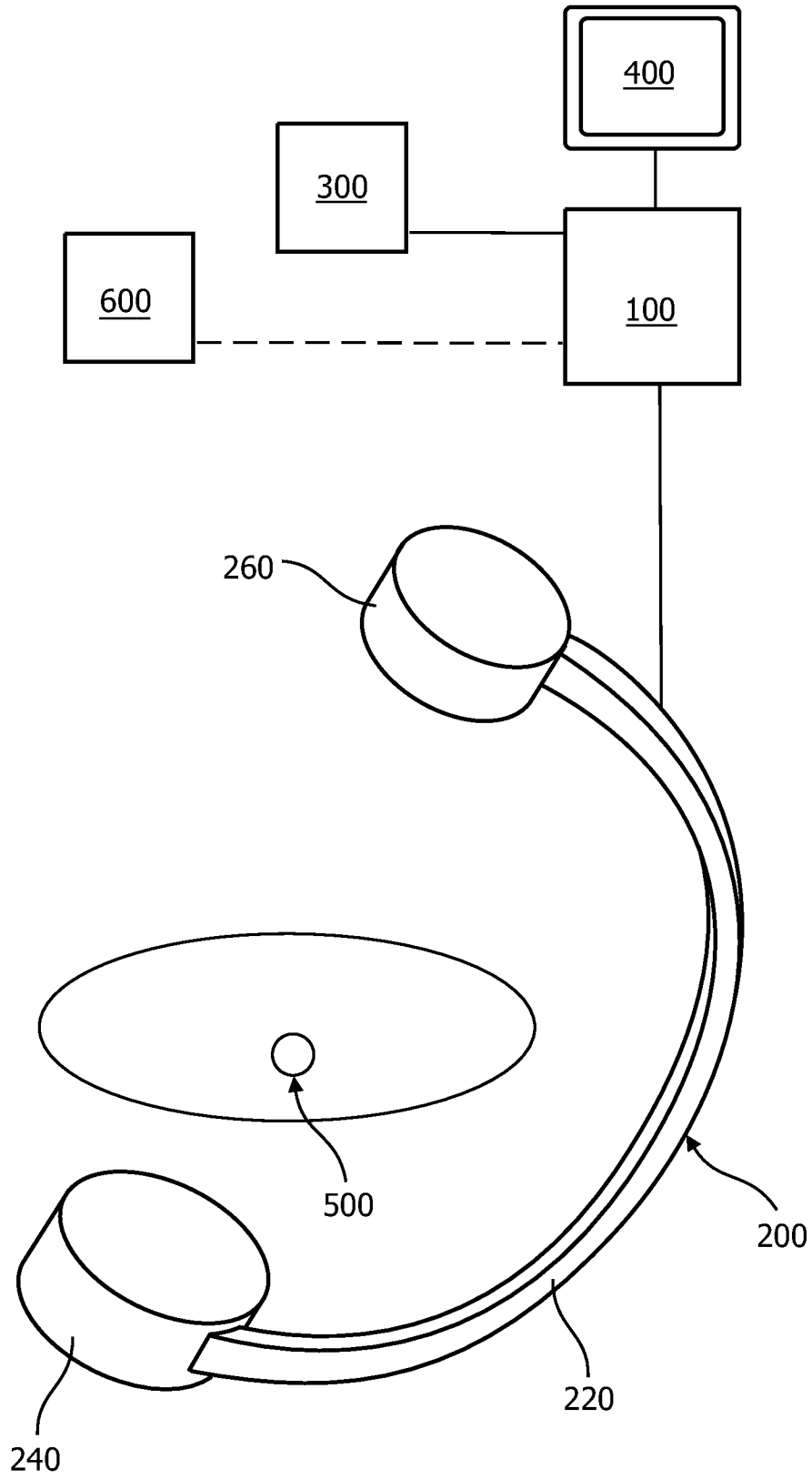


FIG. 2



FIG. 3

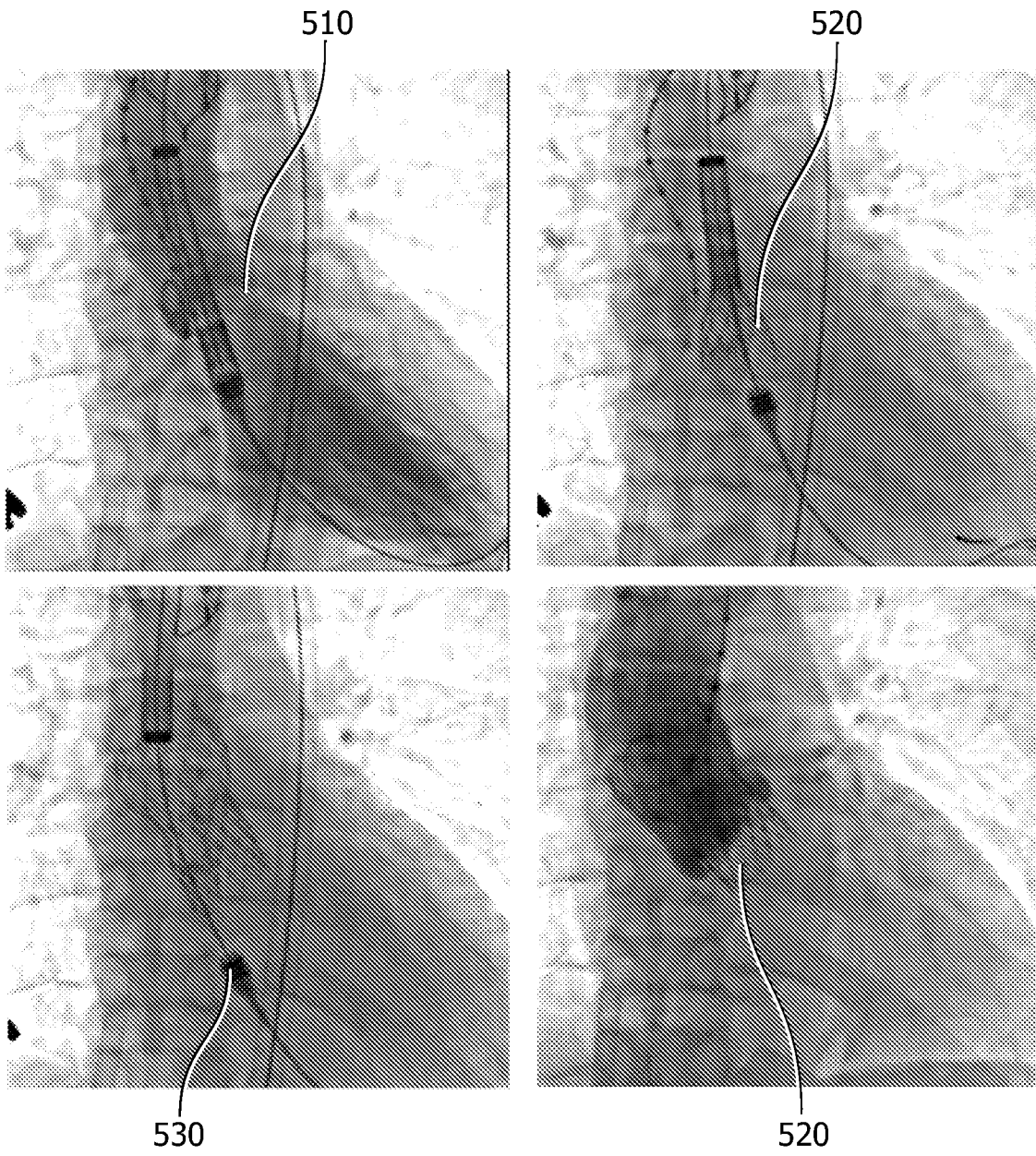


FIG. 4

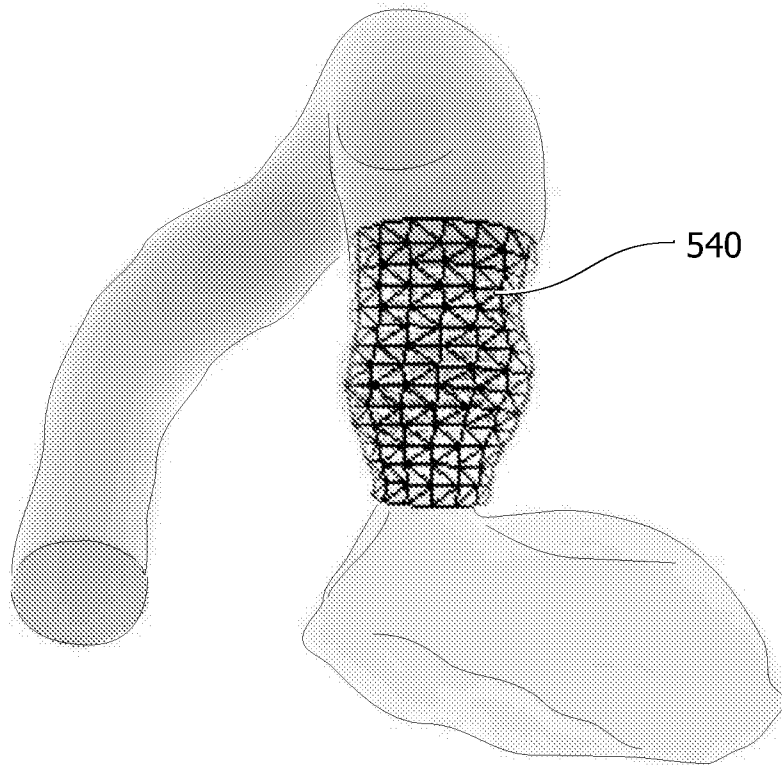


FIG. 5