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(54) Title: CATHETER FOR OBTAINING THREE-DIMENSIONAL RECONSTRUCTION OF A VASCULAR LUMEN AND WALL, AND METHOD OF USE

(57) Abstract

A catheter system and method of use thereof to obtain accurate three-dimensional reconstruction of a body vessel. The method employs X-ray angiography (ANG) in combination with intravascular ultrasound (IVUS) to overcome limitations existing in present three-dimensional reconstruction techniques using a method termed ANGUS. The IVUS data represent a cylindrical stack of cross sections. A 3-D path of the catheter axis is reconstructed from two X-ray images, after which the stack of IVUS contours is wrapped around this 3-D catheter centerline. In order to establish the correct rotational position of the stack around the centerline, use is made of "landmarks" or catheter features which are visible in angiograms, as well as in a simulation of these angiograms derived from the reconstructed 3-D contour.

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DESCRIPTION

Catheter For Obtaining Three-Dimensional Reconstruction Of A Vascular Lumen And Wall, And Method Of Use

This is a continuation-in-part of copending U.S. Application Serial No. 08/600,140, filed February 12, 1996, the contents of which are incorporated herein by reference.

5 ### Field of the Invention

This invention relates to ultrasound imaging of a body passageway, and particularly to a catheter system and methods for obtaining three-dimensional reconstruction of a vessel by X-ray angiography and intravascular 10 ultrasound.

Background of the Invention

From a sequence of IVUS images, acquired during automated, constant-speed pull-back, a 3-D image of a coronary artery can be reconstructed, by stacking the 15 acquired frames along a straight axis. This kind of reconstruction is described in the literature (Roelandt et al., "Three dimensional reconstruction of intracoronary ultrasound images - Rationale, approaches, problems and directions," Circ. 90(2):1044-1055, (1994), this and all 20 other references cited herein are expressly incorporated by reference as if fully set forth in their entirety herein) and some commercially available IVUS systems have such a possibility built in. However, in these images, the straight orientation of the vessel segment is a 25 simplification, because the catheter tip will in reality traverse a spatial curve, the effect of which is hidden from the observer.

The approach of spatial curve reconstruction based on successive single point reconstructions of the catheter's

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tip trajectory has been chosen by many investigators. A recent article describing 3-D reconstruction based on McKay's algorithm for single point reconstruction is from: Evans et al., "Accurate three-dimensional reconstruction

5   of intravascular ultrasound data," Circulation 93:567-576 (1996). In this article, it is described how, during pull-back, the echo transducer position is repetitively imaged (20-31 times) by biplane X-ray to determine a series of discrete positions of its 3-D path. The authors

10   triggered for ECG and respiration to get similar vessel position at subsequent image acquisitions but, despite these measures, this method is prone to get artifacts because of differences in the respiratory and cardiac cycles. Furthermore, in the current reconstruction

15   methods no solution has been provided to reconstruct the correct rotational orientation of the acquired cross-sectional images in the imaging plane once the position and orientation of the plane has been determined.

Brief Summary of the Invention

20   To overcome these limitations, a method was developed using data obtained from ANGiography and intravascular UltraSound (ANGUS). Slager et al., The Thoraxcenter Journal 7/3:36-37 (1995). This technique provides real spatial geometry and orientation of a vessel, i.e., of the

25   lumen and wall. The vessel is studied by IVUS during a pull-back of the IVUS catheter at a speed of, for example, 1 mm/s. Start and end of the pull-back are recorded by biplane fluoroscopy and, finally, biplane angiography is performed without changes in geometrical X-ray settings.

30   Using a computer program, the contours of the lumen-wall and wall-adventitia boundaries are semi-automatically detected at, for example, 0.5 mm intervals. Biplane fluoroscopy allows geometrical reconstruction of the catheter centerline, which, in the

35   case of a sheath-based catheter, is the path of the IVUS transducer during pull-back. Combined use of the IVUS

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data, the catheter path, and the lumen contours in the biplane angiography provides a 3-D reconstruction of vessels without any evidence of an additional unknown geometric factor. Studying the trajectory in a vessel

5   phantom of known dimensions a high accuracy was found (distance between reconstructed and real trajectory at any point <2 mm). First application in a human right coronary artery *in vivo* (length: 75 mm) showed a difference of 2% between the length of the reconstructed trajectory and the

10   pull-back distance. Checking the locations of the origin of side branches in the 3-D reconstruction and biplane angiography, differences of less than 2 mm were found. Location and shape of stenoses in simulated projections of the reconstructed lumen matched well with biplane

15   angiography. However, at the site of a previous PTCA, luminal haziness in angiography and dissection observed by IVUS may slightly reduce the accuracy of this technique.

Thus, combining X-ray ANGiography and intravascular UltraSound (ANGUS) is a substantial improvement and

20   provides a unique reconstruction of 3-D coronary geometry. In one method, X-ray angiography is combined with a stack of intravascular ultrasound (IVUS) images to obtain a 3-D reconstruction of a vessel. In another method, X-ray angiography is combined with "contour tracking" or border

25   tracking as discussed in Li et al., "Image segmentation and 3D reconstruction of intravascular ultrasound images," In: "Acoustical Imaging," ed. Y. Wei and B. Gu, Plenum Press, New York (1993) to obtain a 3-D reconstruction of the vessel-blood interface and/or the wall-adventitia

30   interface.

The present invention also contemplates a catheter system for imaging a vessel to obtain three-dimensional reconstruction, and which is specially adapted for ANGUS imaging in accordance with the invention. In one embodi-

35   ment, the catheter system includes an elongate sheath having proximal and distal regions, wherein the distal region houses an ultrasound transducer and permits

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rotation and longitudinal translation in order to obtain
a stack of two- dimensional or cross-sectional ultrasound
images during pull-back. The sheath further comprises a
series of radiopaque markers, wherein the number of

5   markers is at least 3, more preferably at least 4, more
preferably still at least 5, more preferably still at
least 6, more preferably still at least 7, more preferably
still at least 8, more preferably still at least 9, and
still more preferably at least 10. The radiopaque markers

10   are disposed about the distal region of the sheath and
spaced by distances along the longitudinal centerline of
20 millimeters or less, more preferably 15 millimeters or
less, more preferably 10 millimeters or less, more
preferably 8 millimeters or less, more preferably 6

15   millimeters or less, and still more preferably 5
millimeters or less. The spacing distance between the
markers determines the accuracy of path interpolation
between successive markers. Because multiple scans will
be obtained between successive markers when the markers

20   are so spaced, a constant rate of pull-back or regular
increments of pull-back can be used to allow calculation
of the transducer position at each scan between markers.

The markers need not be equally spaced from one
another, but in certain preferred embodiments, the markers

25   are equally spaced along the longitudinal centerline. The
radiopaque markers can be selected from any radiopaque
materials well known in the art, and in preferred
embodiments will comprise thin metal rings mounted on the
distal region of the sheath. Alternatively, the

30   radiopaque markers will consist of doping material
incorporated into the distal region of the sheath. The
markers are primarily intended to speed up the 3-D
reconstruction of the catheter centerline which allows use
on line and makes the method more robust. The markers

35   allow use of a point reconstruction algorithm after which
a line is interpolated through the reconstructed marker
points.

5

In another embodiment, the markers are spaced in a manner that allows use of the effects of the markers in the ultrasonic images as an aid to provide positional feedback during pull-back. For this embodiment, the width of the markers should be no greater than 2 mm, more preferably 1 mm, more preferably 0.5 mm, more preferably 0.3 mm. The space left between markers should be at least 0.8 mm, more preferably 1 mm, more preferably 1.5 mm, more preferably 2 mm, more preferably 3 mm, and up to 20 mm in accordance with spacing as discussed elsewhere herein.

Where images are acquired at successive markers, the markers must be at least partially echotransparent. If the markers are only weakly radiopaque so as to be just visible, the echo-image behind the markers can be used; if the markers are not transparent, then the spaces in between the markers can be used for imaging. In this case, the spacing should at least allow the ultrasound beam to pass without causing reflections at the edges of the markers, so as to prevent interference of the markers with the beam.

In case of, for example, a manually-applied pull-back, close spacing of markers enables reconstruction of body passages in which no triggering of the pull-back is used. When using closely spaced markers, a loss in X-ray resolution by overlap of the markers may occur, especially where the centerline is viewed by X-ray at a sharp angle. Thus, it may be desired to highlight every fourth, sixth, eighth, or tenth marker so that the X-ray image can be used to reconstruct a path based on more widely spaced markers.

During image reconstruction, a cross-sectional image is first placed at the correct position along the reconstructed centerline. Then, the image is oriented in a plane perpendicular to the centerline at that position. In a final step, the rotational orientation of the IVUS image in the imaging plane should be adjusted to obtain an optimal 3-D reconstruction. Adjustment of rotational

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orientation is illustrated in Figures 9A and 9B which show
centerline 5 and cross-sectional image 6 at two different
rotational orientations. In other preferred embodiments
which permit rotational adjustment, the multiple markers
5   on the sheath are arranged into a helical pattern, such
that at least a one-half turn is obtained over the path
being investigated. This allows the use of features of
the X-ray image showing differences in opacity which is
dependent on the intersection of the beams with the
10 markers. Information thus obtained can be combined with
features in the ultrasound image to deduce a correct
rotational orientation of the ultrasound transducer in the
imaging plane.

        In other preferred embodiments, the distal region of
15 the sheath includes at least one acoustical indexing
marker which can optionally extend longitudinally parallel
to the longitudinal centerline. The distal region of the
sheath should be shaped to receive an imaging core
comprising an ultrasound transducer operably disposed on
20 a drive shaft or, optionally, an imaging catheter having
an ultrasound transducer operably disposed at a distal
region thereof. Where an imaging catheter is used in
combination with the sheath, it is desirable that the
imaging core, drive shaft, or imaging catheter be
25 substantially more flexible than the elongate sheath. It
is also desirable for the imaging core, drive shaft, or
imaging catheter to include an opaque orientation marker
which is radially fixed relative to the ultrasound
transducer and which enables X-ray visualization of the
30 rotational orientation of the transducer. In other
embodiments, it is desirable for the transducer to further
include a radiopaque component which enables visualization
during the angiographic procedure.

        In another preferred embodiment, the catheter system
35 includes the components described above, except that the
sheath having radiopaque markers is replaced by a sheath
having a gradual change in X-ray radiopacity along the

longitudinal centerline, this effect commonly known as a gray scale variation. In accordance with technology known in the art, gray scale radiopacity generally comprises doping material incorporated into the distal region of the

5 sheath. In other preferred embodiments, the catheter system includes a sheath having at least one acoustical indexing marker disposed about the distal region, wherein the indexing marker preferably extends longitudinally parallel to the longitudinal centerline.

10 In another preferred embodiment, the catheter system includes an ultrasound transducer operably disposed on a drive shaft, wherein the drive shaft has a plurality of radiopaque markers disposed about the distal region of the drive shaft. The number of markers and the spacing are as

15 described above. When the drive shaft is disposed in the sheath during operation, these markers will allow 3-D reconstruction of the catheter path. Marker arrangement in a helical pattern might be useful for reconstruction of the transducer rotational orientation.

20 In another preferred embodiment, the catheter system includes an elongate sheath and a guidewire operably disposed within the distal region of the sheath, wherein the guidewire has a longitudinal centerline and a plurality of radiopaque markers disposed about a region of

25 the guidewire which can be positioned during angiography in an area of interest. In accordance with this embodiment, the guidewire may include 3, 4, 5, 6, 7, 8, 9, or more radiopaque markers, and the markers should be spaced by distances of no greater than 20 millimeters,

30 more preferably no greater than 15 millimeters, more preferably no greater than 10 millimeter, more preferably no greater than 8 millimeters, more preferably no greater than 6 millimeters, and more preferably still no greater than 5 millimeters along the longitudinal centerline.

35 Although the markers need not be separated by equally spaced distances along the longitudinal centerline, in preferred embodiments, the radiopaque markers are

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separated by equally spaced distances. The radiopaque
markers may alternatively consist of thin metal rings
mounted on the distal region of the guidewire, local
attachment of radiopaque dots into the distal region of
5   the guidewire, or a gray scale pattern as produced by
doping material incorporated into the guidewire. In
another embodiment, the catheter system includes at least
one acoustical indexing marker disposed about the distal
region of the sheath, and preferably extending
10   longitudinally parallel to the longitudinal centerline.
In the case of markers on the guidewire or on the drive
shaft, the markers may consist of relatively wide bands
having, for example, a width equal to the spacing distance
between bands.

15   The present invention also includes methods for using
a catheter having an ultrasound transducer and a
longitudinal centerline in order to obtain accurate
three-dimensional reconstruction of a body passageway,
including a vessel. Such methods include the steps of
20   obtaining a stack of cross-sectional ultrasound images,
obtaining contours from those images at interfaces of
different tissues, obtaining X-ray images of the catheter
during pull-back, and combining the stack of cross-
sectional ultrasound images and/or the derived interface
25   contours with the geometry of the spatially reconstructed
catheter longitudinal centerline thus determined to
produce a reconstruction of a vessel. The three-
dimensional geometry of the longitudinal centerline may be
determined either by serial monoplane imaging or by
30   obtaining a set of biplane X-ray images. In one preferred
embodiment, the X-ray image acquisition of the centerline
should be triggered by respiration and/or electro-
cardiogram. In another preferred embodiment, the
ultrasound images are obtained at locations separated by
35   equally spaced distances along the longitudinal
centerline, such distances having a correlation to the
location of each radiopaque marker along the catheter

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sheath. In other preferred embodiments, respiration-gated image acquisition and/or electrocardiographic-gated image acquisition is employed such that cardiac and respiratory movement are effectively eliminated in order to reduce

5   distortions in the ultrasound images. During the cardiac and respiratory cycles, the catheter will periodically change location relative to the vessel. However, by gating the ultrasound image acquisition on both cycles, e.g., at end-diastole and end- expiration, it will be

10 possible to capture images for which the three-dimensional location may be derived from the once recorded centerline location.

In another preferred embodiment, the pull-back may be applied step-wise each time after the ultrasound image has

15 been acquired in an ECG and respiration triggered mode.

In another preferred embodiment, the stack of cross-sectional ultrasound images or contours is produced by placing individual frames of ultrasound images or contours derived from these images in correspondence with

20 the geometry of the longitudinal centerline such that each frame lies in a plane disposed at a ninety degree (90) angle to the longitudinal centerline. When positioning the stack of cross-sectional images along the longitudinal centerline, it is preferred to determine the correct

25 rotational position of the stack around the centerline. Landmarks within the vessel may be visible through X-ray contrast angiography and can be exploited for this purpose. Also, the position of the centerline relative to the lumen contrast contours should correspond with that of

30 the centerline in the reconstruction relative to the reconstructed lumen border. Alternatively, an external ultrasound source with a known direction can be used to determine the correct rotational position because the external source provides direction-sensitive interference

35 with the stack of ultrasound images obtained during pull-back.

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Brief Description of Drawings

Figure 1 depicts a preferred embodiment of a catheter according to the present invention;

Figure 2A is a cross-sectional view through section line 2-2 of the catheter depicted in FIG. 1;

Figure 2B is an alternative cross-sectional view through section line 2-2 of the catheter depicted in FIG. 1;

Figure 3 depicts an alternative distal region of the catheter depicted in FIG. 1;

Figure 4 depicts an alternative distal region of the catheter depicted in FIG. 1;

Figure 5 is a 3-D view of the stack of smoothed IVUS cross- sections (Z-axis not to scale). Dark surface: external elastic membrane; light surface: vessel lumen;

Figure 6 shows how the twist of catheter tip depends on the course of the spatial curve. The top point at 12 o'clock has become the forward point at 9 o'clock;

Figure 7 is a rendering of a reconstructed *in vivo* vessel;

Figure 8 shows how the position of a sclerotic plaque in an inside bend (a) or outside bend (b) influences its extent, without a marked change in IVUS image (c);

Figure 9A depicts a single IVUS cross-sectional image which is positioned along the reconstructed centerline and oriented in a single imaging plane;

Figure 9B shows adjustment of the rotational orientation of the IVUS image in the imaging plane.

Detailed Description of the Invention

To improve on three-dimensional reconstruction of vessels, we added a method to reconstruct the spatial curve traversed by the catheter tip using a biplane X-ray image of the catheter at the start of the pull-back procedure.

We apply, as a first step, the same IVUS technology during an automated pull-back of a sheathed IVUS catheter

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at a speed of, for example, 1 mm/second or, in case of triggering by the ECG and respiration, in, for example, 1 mm steps. Start of the pull-back procedure is recorded by biplane X-ray. At least one set of biplane images should
5   be acquired showing the catheter centerline at end-diastole and end-expiration. The IVUS catheter tip will follow the sheath closely during pull-back and the sheath itself will keep its relative position within the artery during this time. At the completion of the
10 procedure, or just after the start of pull-back, biplane coronary angiography is performed without any change in geometrical X-ray settings. The biplane X-ray images, showing the catheter position shortly after start of pull-back, allow geometrical reconstruction of the
15 position of the catheter's longitudinal centerline, which is assumed to represent the path of the catheter tip during pull-back.

       From the IVUS images, end diastolic samples are selected and, from these, the contours of the lumen wall
20 and external elastic membrane are semi-automatically detected (Li et al., "Image segmentation and 3D reconstruction of intravascular ultrasound images," In: "Acoustical Imaging," ed. Y. Wei and B. Gu, Plenum Press, New York (1993)). These contours are stacked and smoothed
25 by removal of the higher frequency components using a 2 dimensional Fourier transform method.

       Finally, these IVUS contours are combined with the reconstructed path of the catheter tip using the features of the angiograms like the position of the catheter
30 centerline relative to the lumen border to establish the rotational position of the IVUS contours around the spatial curve.

       A catheter for use herein will comprise an elongate sheath having proximal and distal ends and at least two
35 regions: a proximal region and a distal region. The elongate sheath has a lumen which is shaped to house an ultrasound transducer in the distal region to permit both

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rotation of the transducer and longitudinal translation to permit ultrasound scanning of a region of a body passageway. Alternatively, the transducer may be carried by an imaging catheter comprising a removable imaging core

5   as described in Sieben, U.S. Patent No. 5,353,798, Crowley et al., U.S. Patent No. 4,951,677, Griffith et al., U.S. Patent No. 5,115,814, and Pomeranz, U.S. Patent No. 5,095,911.   The sheath further includes one or more radiopaque markers spaced along the longitudinal

10 centerline of the sheath within the distal region to facilitate X-ray visualization while the catheter is operated within a body passageway. In another embodiment, the sheath operates with a guide wire in an over-the-wire design or in a monorail design as known in the art and

15 described in Goodin et al., U.S. Patent No. 4,928,693, Leary et al., U.S. Patent No. 5,024,234, Horzewski et al., U.S. Patent No. 4,748,982, and Bonzel, U.S. Patent No. 4,762,129, and the guidewire includes a plurality of radiopaque markers. Alternatively, the sheath may include

20 a gradual change in X-ray radiopacity, such as a gray scale pattern, to indicate the position of the sheath during operation within a body passageway.

In use, the catheter will be advanced into a patient's body passageway until the distal region of the

25 elongate sheath lies within a region of interest.   A guidewire may be used to assist advancement of the catheter into the passageway. The region of interest may be a region of a blood vessel which has been narrowed by a stenotic lesion. Once the catheter sheath is in place,

30 in one embodiment the transducer is adjusted longi- tudinally so that it is aligned with a radiopaque marker, and preferably with the first or last marker where the sheath includes a plurality of markers. Such alignment can be achieved either by using ultrasound from the

35 transducer to visualize the location of the marker, or by obtaining X-ray images of the catheter and aligning the marker with a radiopaque component fixed to the

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transducer. In another embodiment, such alignment is not required. Just making an X-ray of the catheter shows the different markers on the sheath as well as the position of the transducer or a radiopaque component fixed to the

5   transducer. Reconstruction of the sheath markers in 3-D as well as the transducer position is then possible and the relative position of the transducer with respect to the sheath markers is known.

    Where a determination of the rotational position of

10 the stack of cross-sectional ultrasound images is desired, an angiographic dye may be injected into the vessel to permit X-ray imaging of the geometric contour of the passageway. Dye injection is performed to show details of the coronary lumen and the relative position of the

15 catheter centerline with respect to the lumen. When the imaging ultrasound catheter with its drive shaft is positioned in the sheath, imaging by X-ray clearly shows the catheter and its centerline, i.e., its drive shaft can clearly be indicated.

20   The transducer is pulled back at a constant rate of speed or stepped at equal distances in case of triggering by the electrocardiogram and/or respiration to obtain a sequence of cross-sectional ultrasound images which can be stacked to obtain a three-dimensional reconstruction.

25 When using a procedure where the longitudinal position of the transducer is referenced only at the outset by a single marker, constant rate or equal step pull-back is important in order to accurately position each cross-sectional image along the path contour as determined from

30 the X-ray images. A three-dimensional reconstruction of the vessel is then obtained by combining the stack of cross-sectional ultrasound images with the geometry of the longitudinal centerline as explained herein.

    Where the sheath includes a plurality of markers,

35 X-ray imaging at the beginning of pull-back allows determination of sheath markers as well as of any transducer (radiopaque) position in the sheath in biplane

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from which the transducer position and the marker positions in 3-D can be reconstructed. In the reconstruction, the cross-sectional ultrasound image captured at the moment of X-raying and/or the contour
5   derived from it must just be positioned at the reconstructed transducer position. Other cross-sectional images and/or contours are stacked relative to this one at distances derived from the pull-back speed or from the increment of steps performed. This procedure may
10 eventually be adjusted by using the information obtained from the ultrasound image at the position of the sheath markers. The latter may be at separation of distances of 20 millimeters or less, more preferably 15 millimeters or less, more preferably 10 millimeters or less, more
15 preferably 8 millimeters or less, more preferably 6 millimeters or less, and still more preferably 5 millimeters or less.

    In accordance with another embodiment, the transducer is first aligned with a radiopaque marker. Then, biplane
20 X-ray imaging is applied to obtain a geometric reconstruction of the longitudinal centerline of the sheath, and ultrasound imaging with pull-back is used to obtain a stack of cross-sectional ultrasound images. Ultrasound data is collected and saved at intervals when
25 the transducer reaches each successive radiopaque marker. Although the markers need not be equally spaced, it is preferred that they are. The width of the markers should be no greater than 2 mm, more preferably 1 mm, more preferably 0.5 mm, more preferably 0.3 mm. The space left
30 between markers should be at least 0.8 mm, more preferably 1 mm, more preferably 1.5 mm, more preferably 2 mm, more preferably 3 mm, and up to 20 mm in accordance with spacing as discussed elsewhere herein.

    Where images are acquired at successive markers, the
35 markers must be at least partially echotransparent. If the markers are only weakly radiopaque so as to be just visible, the echo-image behind the markers can be used; if

15

the markers are not transparent, then the spaces in between the markers can be used for imaging. In this case, the spacing should at least allow the ultrasound beam to pass without causing reflections at the edges of

5   the markers, so as to prevent interference of the markers with the beam. In case of, for example, a manually-applied pull-back, close spacing of markers enables reconstruction of body passages in which no triggering of the pull-back is used. When using closely

10 spaced markers, a loss in X-ray resolution or overlap of the markers may occur, especially where the centerline is viewed by X-ray at a sharp angle. Thus, it may be desired to highlight every fourth, sixth, eighth, or tenth marker so that the X-ray image can be used to reconstruct a path

15 based on more widely spaced markers.

After a stack of two-dimensional ultrasound images is obtained and/or the contours at the lumen wall and wall-tissue border have been determined, a three-dimensional reconstruction of the interior lumen and

20 wall/tissue environment of a body passageway is produced by combining the stack of cross- sectional images and/or the contours with the geometry of the longitudinal centerline of the sheath, which approximates the geometry of the path followed by the ultrasound transducer. First,

25 the geometry of the longitudinal centerline is determined from the X-ray image data. The spatial position of a single Roentgen-opaque marker-point registered by a biplane X-ray imaging unit can be reconstructed from its two projections. Two slightly different methods exist for

30 such reconstruction. First, during image acquisition, the position of the image intensifier entrance screen and X-ray focus are registered in an x, y, z coordinate system defined in the room containing the imaging equipment. The geometric enlargement of the imaging chain from image

35 intensifier entrance screen up to the final digitized computer image is calibrated by imaging a calibration grid at the entrance screen having exactly known dimensions.

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From the registered geometrical coordinates and the calibration data, the relationship between the coordinates of a marker-point in space and its coordinates in the biplane projections can be mathematically derived using
5 well-known mathematical techniques. This implies that when the coordinates of a point in its two projections are known, the spatial coordinates in x, y, z can be determined. See, e.g., "Image reconstruction from biplane angiographic projections," Dumay, A.C.M., Ph.D. Thesis,
10 Technical University Delft (1992), ISBN 90-9005432-4.

A second method for point reconstruction, slightly different from the above, uses a calibration cube containing multiple radiopaque markers with known positions. This technique does not make use of a
15 registration of the position of the X-ray focus and image intensifier entrance screen. For a certain position and orientation of the imaging chain's components, it uses the two projection images of the cube's markers to determine a transformation matrix describing the relation between
20 the spatial coordinates of a marker and its coordinates in the projection images. Using the inverse of this matrix, the spatial position of a marker imaged by the identically-oriented imaging chain can be reconstructed from its coordinates as derived from both projections.
25 See, e.g., McKay et al., "Graphic methods for tracking three-dimensional heart wall motion," Comput. Biomed. Res. 15:455-473 (1982).

In another ANGUS approach not requiring a plurality of markers along a centerline, a single pair of images
30 (simultaneous biplane or sequential monoplane) showing the catheter's imaging core is used to reconstruct the complete pull-back path. These images are taken at end-expiration and end-diastole. Digitization of the catheter images involves indication of the catheter
35 centerline in both projections. These lines are stored as a series of positions in a computer. The digitized positions in the different projections cannot be simply

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paired as the catheter images do not provide unique points
which can be identified in both projections. Only two
unique points, i.e., the echotransducer position and the
catheter tip, can be identified in both projections.
5   Therefore, in this case, we need a slightly different
approach to reconstruct a spatial curve representing the
catheter's centerline covering the complete pull-back
trajectory. For this reconstruction of the catheter path
from its projections, we apply routines written in MATLAB
10 (The Math Works, Inc., Cochituate Place, 24 Prime Park
Way, Natick, Massachusetts) language. A more detailed
description of the applied algorithms is described in
Laban et al., "ANGUS: A new approach to three-dimensional
reconstruction of coronary vessels by combined use of
15 angiography and intravascular ultrasound," Computers in
Cardiology, IEEE Comp. Soc., 325-328, (1995). Briefly, we
make a reasonable description of some spatial curve in
Fourier parameter description which represents a first
approximation of the searched catheter centerline in the
20 x, y, z space. The projection images of this centerline
are next calculated using the inverse of one of the
two-point reconstruction methods described above. In the
projection plane, a comparison is being made between the
projections of the first centerline approximation and the
25 actual digitized centerline projections. On base of this
comparison, a cost function is defined which accounts for
the differences between the projections. Then a
correction is applied on the parameter description to
improve matching of the simulated and the real
30 projections. In a series of subsequently improved
approximations, the cost function will be minimized until
an accurate description of the catheter in 3-D is
obtained. Additional information obtained from the
uniquely defined position of the imaging transducer
35 enables the selection of a specific point on this curve,
i.e., the position of the crystal at the moment of X-ray
application. From this point, subsequent transducer

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positions during pull-back can be derived as the pull-back
is performed by a precisely controlled motorized system.

For vessel reconstructions to be used for quanti-
tative purposes, we combine a stack of cross-sectional
5   border lines at the lumen wall and wall adventitia
interface derived from intravascular images which were
captured during pull-back. Each cross-sectional contour
belonging to an imaging plane has to be positioned in the
x, y, z space on the reconstructed catheter centerline.
10 The location of the imaging plane is derived from the
pull-back speed and the uniquely X-ray-registered
transducer position. The orientation of the image plane
is chosen perpendicular to the centerline. Finally, the
rotational position of the contour in the imaging plane
15 has to be determined (Figures 9A and 9B). The latter is
described in more detail in Laban et al., "ANGUS: A new
approach to three-dimensional reconstruction of coronary
vessels by combined use of angiography and intravascular
ultrasound," Computers in Cardiology, IEEE Comp. Soc.,
20 325-328, (1995), and Slager et al., "Three-dimensional
geometry and orientation of coronary lumen and plaque.
Reconstruction from angiography and ICUS (ANGUS)," Thorax-
center Journal, pages 36-37 (1995), and includes a path
dependent correction for twisting of the catheter which
25 introduces a change in the rotation of the contours
between successive cross-sections. The optimal rotational
position is determined at hand of a comparison with the
biplane contrastangiograms which have been taken during
pull-back at end diastole and end respiration. These
30 contrastangiograms show the position of the intravascular
imaging catheter relative to the vessel lumen and the
vessel lumen itself over a few cardiac cycles. For the
selected geometry of the applied X-ray projections,
corresponding shadow images of the reconstructed lumen
35 borders and the catheter centerline are calculated for a
set of rotational positions of the cross-sectional images.

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By comparing those images with the contrastangiograms, the optimal rotational position can be selected.

In alternative embodiments, angiography may be omitted if the radial position of the stack of images
5 around the reconstructed longitudinal centerline can be derived from, for example, the helical arrangement of the sheath markers, or from the radial orientation of a radiopaque element (for example, a small opaque disk), radially fixed to the transducer. Such an element can be
10 documented during rotation by X-ray filming. Orientation of the element can thus be derived from the X-ray images and used to determine the orientation of the simultaneously captured ultrasound cross-sectional images.

Using a catheter with multiple sleeve or sheath
15 markers provides an improvement to the latter-described method and enables on-line application of 3-D path reconstruction. Using either of the reconstruction methods described above, the x, y, z position of individual markers can be reconstructed from the
20 projection images. Subsequently, an approximated catheter centerline can be calculated by applying a spline (standard math lab routine) fitting through these points.

Figure 1 depicts one example of a preferred catheter for use in accordance with methods disclosed herein. The
25 catheter has an elongate sheath 12, which comprises proximal region 15 and distal region 18. Figures 2A and 2B are cross-sectional views of the distal region of sheath 12 through section line 2-2 according to alternative embodiments. Guidewire port 30 and work
30 element port 32 (Figure 1) place lumen 25 in communication with the exterior of the catheter near its proximal end. Drive shaft 45 is reciprocatably disposed within lumen 25, and carries ultrasound transducer 46 at its distal tip. (For clarity, only the distal portion of drive shaft 45 is
35 illustrated.) At its proximal end, lumen 25 is in communication with expandable member 39, which is connected in turn to proximal housing 35. The proximal

20

housing is adapted to connect a proximal end of drive
shaft 45 to a drive motor (not shown) for rotating the
drive shaft. Expandable member 39 allows the drive shaft
to be advanced and retracted within lumen 25 by moving
5   proximal housing 35 with respect to the elongate sheath to
lengthen or shorten expandable member 39 as desired. The
construction and use of proximal housing 35 is fully
described in Salmon et al., U.S. Patent No. 5,314,408.

      The distal region 18 of sheath 12 includes a distal
10 tip 60 and radiopaque markers 68 wrapped around or
integral with sheath 12 to enable fluoroscopic imaging to
assist in determining the geometry of the longitudinal
centerline of the sheath. Because these markers are also
visible by ultrasound, these markers enable the operator
15 to correlate the transducer position relative to each
marker for each image with a precise anatomical/vessel
location as determined fluoroscopically. The length of
distal region 18 will generally be between 5 and 30
centimeters, and the minimum width crossable by the
20 elongate sheath will typically be in the range of
0.020-0.045 inches. The foregoing ranges are intended
only to illustrate typical device dimensions, and the
actual dimensions may obviously vary outside of the stated
ranges without departing from the basic principles
25 disclosed herein.

      A cross-section through distal region 18 of sheath 12
through line 2-2 is depicted in Figures 2A and 2B. As can
be seen therein, acoustical indexing markers or rotational
compensation markers 92 can be incorporated circumfere-
30 ntially into the wall of sheath 12 in the distal region
18. The markers 92 may be splines or patterns incorpo-
rated on the interior surface of sheath 12, as depicted in
Figure 2A, or on the exterior surface of the sheath, as
depicted in Figure 2B. The inclusion of acoustical
35 indexing markers and the considerations therefore are
fully discussed in Sieben et al., U.S. Patent No.
5,243,988, and will not be repeated here.

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Figure 3 depicts an alternative embodiment which shows the distal region 18 of sheath 12 having distal tip 60. In this embodiment, the radiopaque metallic rings are replaced by a gray scale pattern 67, or other pattern to

5   indicate a change in position between the sheath and the transducer. The pattern can be applied over just the distal length 18 on the sheath, or over the entire length. Such patterns are fully discussed in Sieben et al., U.S. Patent No. 5,243,988.

10   Figure 4 depicts an alternative embodiment which shows distal region 18 of sheath 12 having distal tip 60. This sheath would permit "monorail" operation as known and discussed in the art. During use, guide wire 90 passes through aperture 91 located proximal of distal tip 60 and

15   distal of proximal region 15 of the elongate sheath 12. The guidewire 90 includes one or more radiopaque markers 68, or a gray scale pattern, which facilitate both geometry mapping by fluoroscopy and determination of transducer position relative to each marker during

20   ultrasound imaging. As discussed above, angiography can be used to fluoroscopically determine vessel geometry. It is apparent that acoustical indexing can be used with the Figure 4 embodiment to further improve three-dimensional reconstruction by allowing the operator to determine the

25   correct rotational position of the stack of cross-sectional images around the longitudinal centerline of the sheath.

A guidewire with radiopaque markers and imaging catheter/core can be used also in an over-the-wire

30   approach as follows: After the imaging catheter/core is retracted from the sheath and stored in the "main" catheter, the marked guidewire can be disposed in the sheath and thus provide a series of markers inside the sheath. These markers can be used to reconstruct the 3-D

35   position of the sheath by the biplane X-ray reconstruction method. After this procedure, the imaging catheter is disposed in the sheath and one more X-ray image at the

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beginning of pull-back will enable reconstruction of the
position of the ultrasonic transducer. Subsequent
transducer positions may be derived from the applied speed
of the pull-back.

5 Example 1 - Processing the IVUS Images
        The IVUS images are recorded during automated
pull-back on a PAL standard S-VHS video tape, resulting in
25 images/second. Other means of pull-back can also be
used, e.g., by applying equidistant pull-back steps
10 triggered by ECG. A few seconds after pull-back has
started, a short biplane X-ray film is made and the start
of this film is marked on the audio track of the S-VHS
tape to enable synchronization with the IVUS contours
sequence. The IVUS picture to be selected is augmented
15 with a marker which indicates the occurrence of the R-peak
in the patient's ECG.
        By filming the position of the catheter shortly after
start of pull- back, any backlash that the automatic
pull-back system might experience has disappeared and a
20 precise relation between the echo image location in the
filmed biplane images and the recorded IVUS pictures can
be established. This is done by locating the ultrasound
transducer or the catheter tip as seen in both of the
biplane film images.
25   Following the acquisition, the S-VHS images are semi-
automatically processed (Roelandt et al., "Three
dimensional reconstruction of intracoronary ultrasound
images - Rationale, approaches, problems and directions,"
Circ. 90(2):1044-1055, (1994)) to detect the contour of
30 both the lumen and the external elastic membrane. Only
images containing the R-peak marker are selected, thus
restricting analysis to the end-diastolic shape of the
artery. The X, Y positions of the detected points are
transferred to a file, together with the R-R interval.
35 The time at which each image was recorded is interpreted
as Z-axis value, making use of the fact that the

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intravascular ultrasound catheter moved at constant speed through the artery.

Using MATLAB, a numeric computation and visualization program, the collected points are resampled at a constant
5 Z-axis interval of 1 second, which translates into 1 millimeter distances between successive cross-sectional images. The contour data are subsequently converted to cylindrical coordinates, thus expressing the vessel wall, as well as the external elastic membrane by $r = f(\varphi, z)$,
10 where r = radius; φ = angle, and z = position along Z-axis. Next, a smoothing algorithm is applied to the surface $f(\varphi, z)$ by removing the higher frequency components of its 2D Fourier transform. The final result is a stack of IVUS cross-sectional images (Figure 5), all
15 aligned perpendicular to and centered around the Z-axis.

Example 2 - Reconstruction of the Centerline

In order to achieve a true 3-D reconstruction of the shape of the vessel, we need to assess the real 3-D path of the IVUS catheter tip. In order to do so, we produce
20 two pictures, showing both of the biplane X-ray images with the position of the IVUS catheter at the start of the pull-back procedure. As stated before, we may assume that the trajectory projections followed by the catheter tip closely coincide with the centerline of the catheter image
25 in its biplane projections.

An alternative to this method would be to record the trajectory of the tip by filming its position many times during pull-back. An investigation of this method showed that a considerable amount of additional movement is
30 superimposed on the catheter path, even when gating for respiration and heart contraction. Therefore, this method is deemed to be less desirable.

After digitization of the biplane projections using a custom-built program, MATLAB routines are used to
35 perform the necessary calculations to reconstruct the true 3-D path of the catheter from its biplane shadow images.

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A first 3-D guess is described in Fourier parameter form. Using an independent variable $(0 \geq s \geq 1)$, the catheter centerline $R(s)$ can be described by:

$$\overline{R}(s) = \overline{a} + \overline{b}.s + \overline{c}.\sin(2\pi.s) + \overline{d}.\cos(2\pi.s) +$$

5
$$\overline{e}.\sin(4\pi.s) + \overline{f}.\cos(4\pi.s) + \ldots \ldots$$

Using a Gauss-Newton optimization method, the parameter vectors $\overline{a}$, $\overline{b}$, $\overline{c}$, $\overline{d}$, $\overline{e}$, $\overline{f}$ . . . are adjusted, such that the projection of the 'guessed' 3-D curve onto each of the image intensifier planes coincides as closely as possible, according to a minimum cost algorithm, with

10 the filmed images of the IVUS catheter centerline.

Although it can be shown that not all possible curves can be reconstructed in this way, due to the existence of 'blind planes': planes that are perpendicular to both of

15 the image intensifier entrance screens, with some caution and experience, it is possible to select a constellation of both image intensifier planes, such that sections of the curve in the 'blind' position are avoided.

Example 3 - Combination of Angio and IVUS Data

20   After having acquired a stack of cross-sections as described in Example 1, and a 3-D centerline as described in Example 2, the stack has to be 'fitted' around the centerline. Because the start signal from the fluoroscopy film camera is recorded on the audio track of the IVUS VHS

25 video, the position of the stack along the centerline is known. It is also known that the resampled stack of cross-sectional images contains pictures at 1 millimeter intervals, measured along the centerline. Two different unknowns, however, have still to be taken into account:

30   a)   Under certain conditions, the catheter tip will exhibit a twist with respect to an external, fixed system of axes (Figure 6).

        b)   The rotational position of the stack of images is unknown.

25

The effect under (a) can be explained as follows. If the catheter itself is assumed to be torsion free, the catheter tip will twist if the curve enters another plane. The amount of twist can be found from the Frenet formulas

5   (Davis et al., "Introduction to Vector Analysis," Wm. C. Brown Publishers, 86:88 (1988)), from which it can be derived that the tip will rotate if the third derivative $(d^3 \ R/ds^3)$ of the parametric curve $R(s)$ does have a non-zero component in a direction perpendicular to both T

10 and N, where T denotes the tangent $(T = dR/ds)$ to the curve $R(s)$ and N denotes the normal $(N = dT/ds)$ to the curve R. Knowing this, one can devise an algorithm that takes this relative rotation, i.e., the rotation from one cross-sectional image to the next, into account. The

15 algorithm we use to reconstruct the 3-D vessel by wrapping successive cross-sectional IVUS images around the reconstructed 3-D catheter centerline, takes the relative rotational differences between successive cross-sections into account by considering the change in local radius of

20 the computed catheter centerline.

This finally leaves us with the problem mentioned under (b). Although the rotation of each vessel cross-section is known with respect to the former one, the rotational position of the first cross-section remains

25 unknown. If we change the rotational position of the first cross-sectional image around the catheter centerline, the whole of the vessel wall will rotate around the fixed and curved centerline. We refer to this phenomenon as 'sock rotation,' because of the similarity

30 of the situation with a sock on a leg.

In order to assess the correct sock rotation, the reconstruction of the 3-D vessel wall is computed for all sock rotations between 0° and 360° in 10° steps. The 2 biplane projections of these 3-D reconstructions also

35 showing the projected centerline reconstruction are then computed resulting in 36 reconstructed biplane frames. While single stepping forward and backward through this

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sequence of pictures, a comparison is made between each of
the computed pictures and the biplane angio as recorded at
the end of the pull-back procedure. Because real vessels
always exhibit landmarks in the form of irregularities,
5 side branches, and bends, and moreover, the catheter
position relative to the vessel wall varies throughout the
pull-back, the most suitable sock rotation can be
estimated from this procedure.

       A final computation is then made to arrive at a full
10 3-D reconstruction of the vessel.

Example 4 - Phantom Study

       In order to assess the accuracy of the method
described here, a phantom has been constructed, consisting
of a plastic cylinder with a diameter of 120 mm, into
15 which we cut a helical groove, with a width of 3 mm and a
depth of 3 mm. The bottom of the groove is semicircular.
The pitch of the groove is 100 mm for one complete 360°
turn. The groove exhibits a D-shaped cross-section. The
groove was filled with saline diluted contrast medium and
20 the aforementioned protocol was followed to obtain the
IVUS images and the biplane X-ray pictures from this
phantom.

       Studying the trajectory within this phantom, a high
accuracy was found, with a distance between real and
25 reconstructed trajectory <1 mm. First application in a
human right coronary artery in vivo (length: 75 mm) showed
a difference of 2% between the length of the reconstructed
trajectory and the pull-back distance. Location and shape
of stenoses in simulated projections of the 3-D
30 reconstructed lumen matched well with biplane angiography
(Figure 7).

       In using the method as described herein, it is
desired to have a high degree of accuracy from the biplane
X-ray installation. We found that errors like
35 non-coinciding isocenters (distance ≈ 2 mm) and a rotation
of the image by the intensifier (≈3°) influenced the

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results noticeably. Nevertheless, due to the best fit
nature of the minimum cost algorithm that is used, we
achieved satisfying results with our first clinical
trials.

5   The advantage of the described method above the
common cylindrical straight reconstruction can be
appreciated if one considers, for instance, the problem of
estimating the extent of plaque material. Although IVUS
will allow an estimation of the thickness of the plaque
10   material, when calculating a volumetric estimate of
sclerotic material, one should take the position of the
plaque relative to the bend of the vessel into account
(Figure 8).

This reconstruction method might also find use in
15   studies where one attempts to reconstruct the flow pattern
in diseased arteries using finite element analysis.

Modifications and variations of the present
invention, and methods of use thereof, will be obvious to
those skilled in the art from the foregoing detailed
20   description.   Such modifications and variations are
intended to come within the scope of the appended claims.

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Claims

1.   A method for imaging a vessel to obtain
three-dimensional vessel reconstruction using a catheter
having an ultrasound transducer and a plurality of
5   radiopaque markers, said method comprising the steps of:
obtaining X-ray images of the catheter during or
at the beginning of pull-back through the vessel to
determine a projected catheter centerline or positions of
the multiple markers on the catheter, and to register a
10   position of the ultrasonic transducer;
obtaining a stack of images, the images being
derived from the ultrasound transducer signal, wherein one
of said images is referenced as relating to the moment of
X-ray capture;
15   calculating from the projected centerline or the
positions of individual markers an approximated catheter
longitudinal centerline in three-dimensional space; and
stacking the images around the longitudinal
centerline by positioning the referenced image at the
20   registered transducer position, and positioning subsequent
images at their respective distances from the referenced
image.

2.   The method of Claim 1, wherein the step of
obtaining a stack of   images includes the step of
25   obtaining a stack of cross-sectional ultrasound images
during pull-back.

3.   The method of Claim 1, wherein the step of
obtaining a stack of images includes the step of obtaining
a stack of contour images at an interface between
30   different tissues.

4.   The method of Claim 1, wherein the step of
obtaining a stack of images includes the step of obtaining
images at equally spaced distances along the longitudinal
centerline.

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5.   The method of Claim 2, further comprising the step of obtaining contours from the cross-sectional ultrasound images at borders between tissues, and wherein the step of stacking cross-sectional images includes
5 stacking the contours around the longitudinal centerline by positioning the contour corresponding to the referenced cross-sectional image at the registered transducer position and positioning subsequent contours at their respective distances from the referenced image.

10   6.   The method of Claim 1, wherein the position of radiopaque markers visible by ultrasound imaging is used to adjust the distance between successively stacked images.

7.   The method of Claim 1, wherein the step of
15 obtaining X-ray images of the catheter during pull-back includes the step of serial monoplane imaging to determine a three-dimensional geometry of the longitudinal center-line of the catheter.

8.   The method of Claim 1, wherein the step of
20 obtaining X-ray images of the catheter during pull-back includes the step of obtaining biplane X-ray images to determine a three-dimensional geometry of the longitudinal centerline of the catheter.

9.   The method of Claim 1, wherein the step of
25 obtaining images includes a stepped pull-back.

10.   The method of Claim 1, wherein the step of obtaining images includes the step of respiration-gated image acquisition.

11.   The method of Claim 1, wherein the step of
30 obtaining ultrasound images includes the step of electrocardiographic-gated image acquisition.

30

12. The method of Claim 1, wherein the stack of images is produced by placing individual frames of images in correspondence with the geometry of the longitudinal centerline so that each of said frames lies in a plane
5 disposed at a 90 degree angle to the longitudinal centerline.

13. The method of Claim 1, wherein the distance between successive images is derived from the respective pull-back distance with respect to the referenced image.

10   14. A catheter for imaging a vessel to obtain three-dimensional reconstruction of a lumen of the vessel, said catheter comprising:
          an elongate sheath having proximal and distal regions, said distal region adapted to enter the vessel
15 while said proximal region extends outside of the vessel to permit control of said catheter, said distal region further adapted to receive an ultrasound transducer and to permit rotation of said transducer and simultaneous longitudinal translation of said transducer to obtain a
20 stack of images during pull-back; and
          at least four radiopaque markers disposed about the distal region of said sheath, said markers spaced by distances of no greater than 20 millimeter as measured along the catheter longitudinal centerline.

25   15. The catheter of Claim 14, wherein said radiopaque markers are separated by equally spaced distances along the longitudinal centerline.

16. The catheter of Claim 14, wherein said radiopaque markers comprise thin metal rings mounted on
30 the distal region of said sheath.

17. The catheter of Claim 14, wherein said radiopaque markers are arranged in a helical pattern along

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said elongate sheath.

18. The catheter of Claim 14, further comprising at least one acoustical indexing marker disposed about the distal region of said sheath.

5   19. The catheter of Claim 18, wherein said acoustical indexing marker extends longitudinally parallel to the longitudinal centerline.

20. The catheter of Claim 14, further comprising an imaging core or imaging catheter adapted to operate within 10   said elongate sheath, said imaging core or catheter having an ultrasound transducer operably disposed at a distal region thereof.
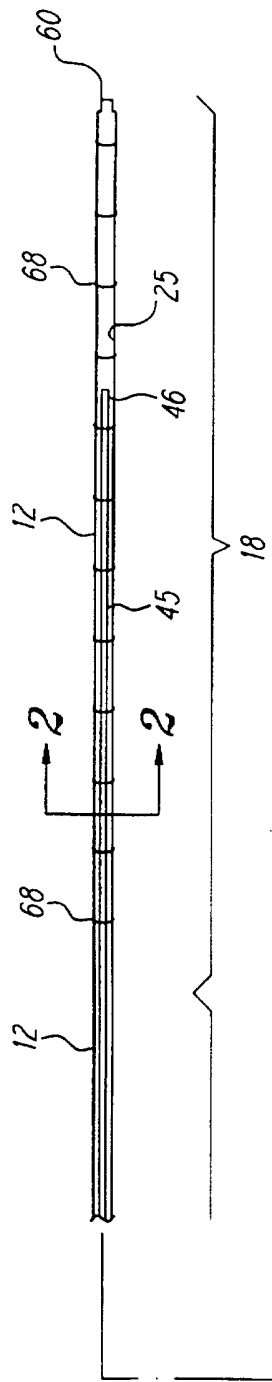
FIG. 1

FIG. 2B

FIG. 2A

FIG. 3

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FIG. 4

FIG. 5.

FIG. 6
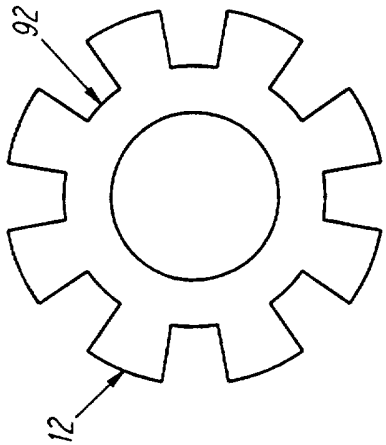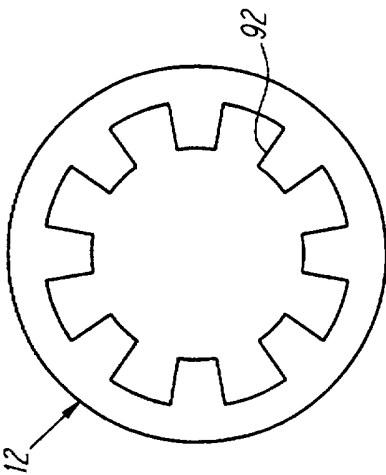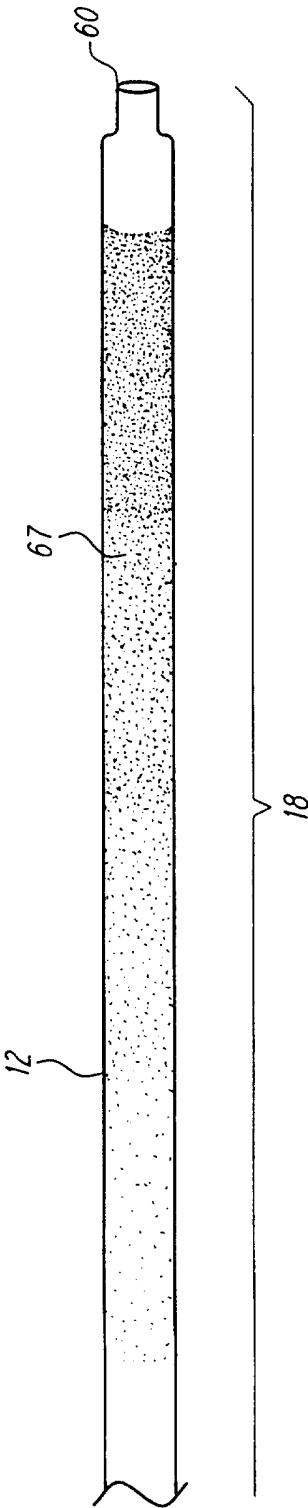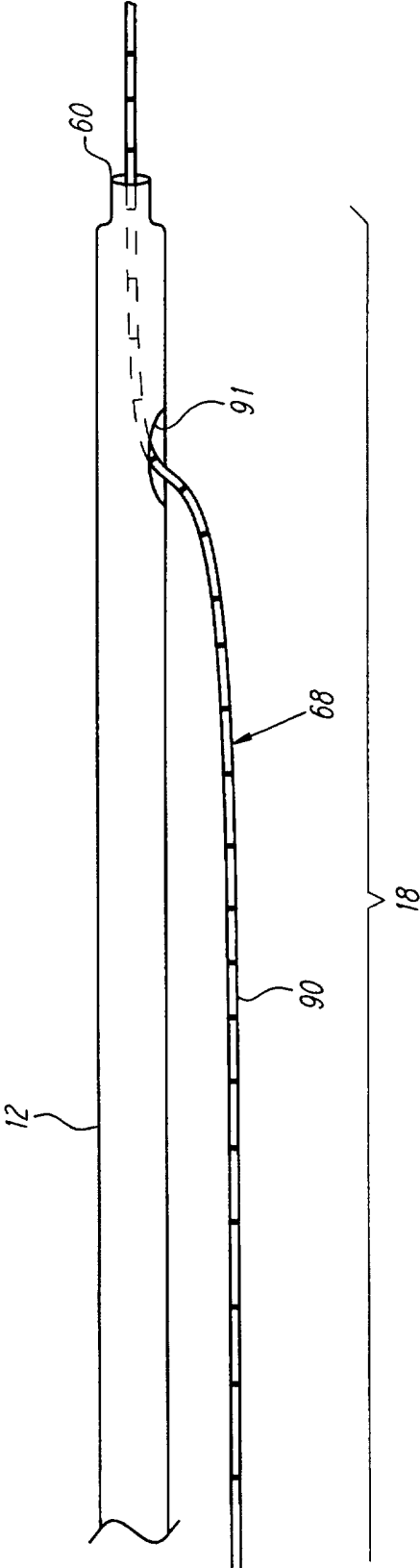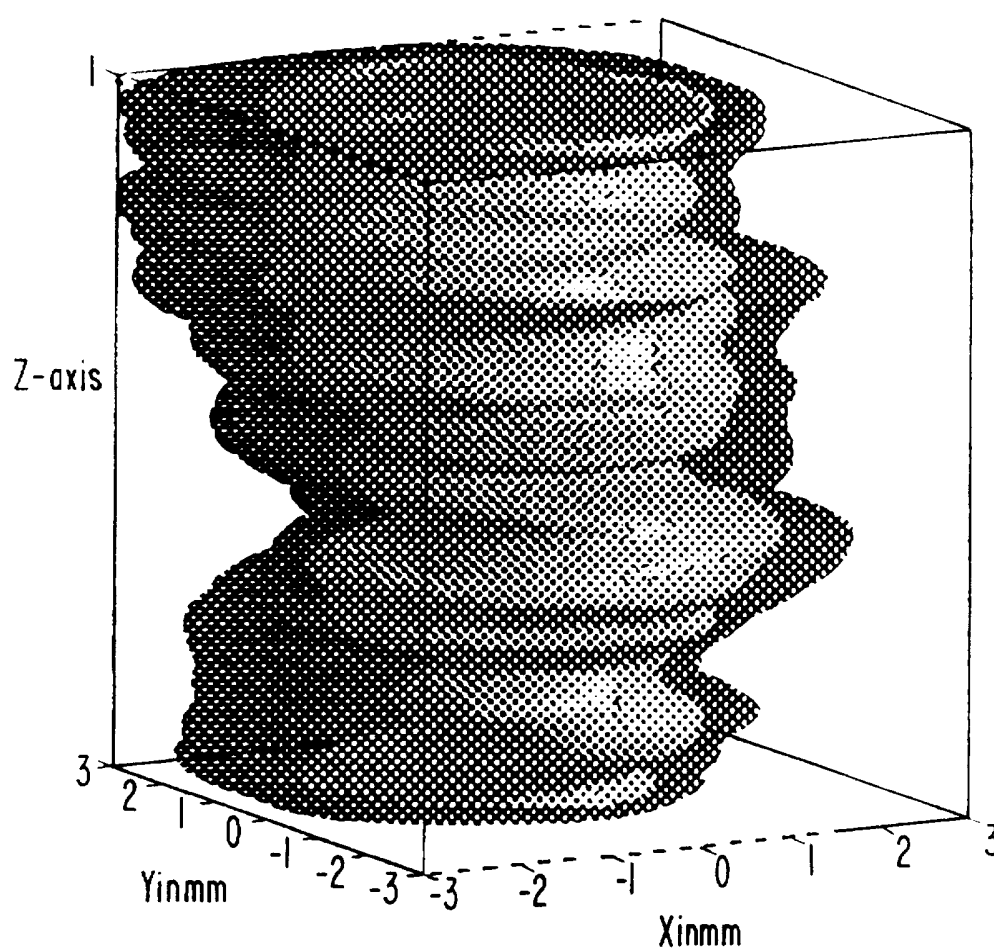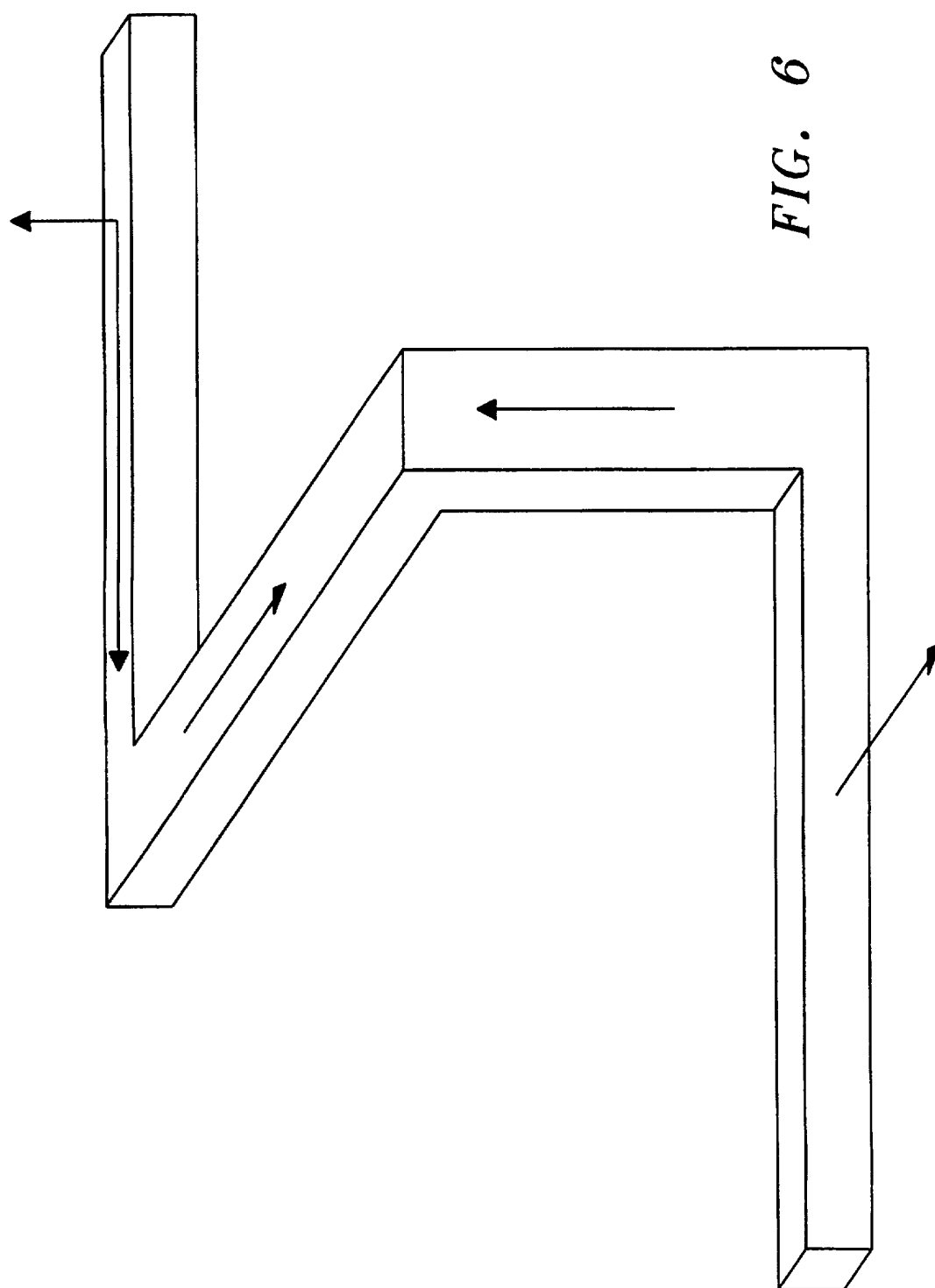
FIG. 7.
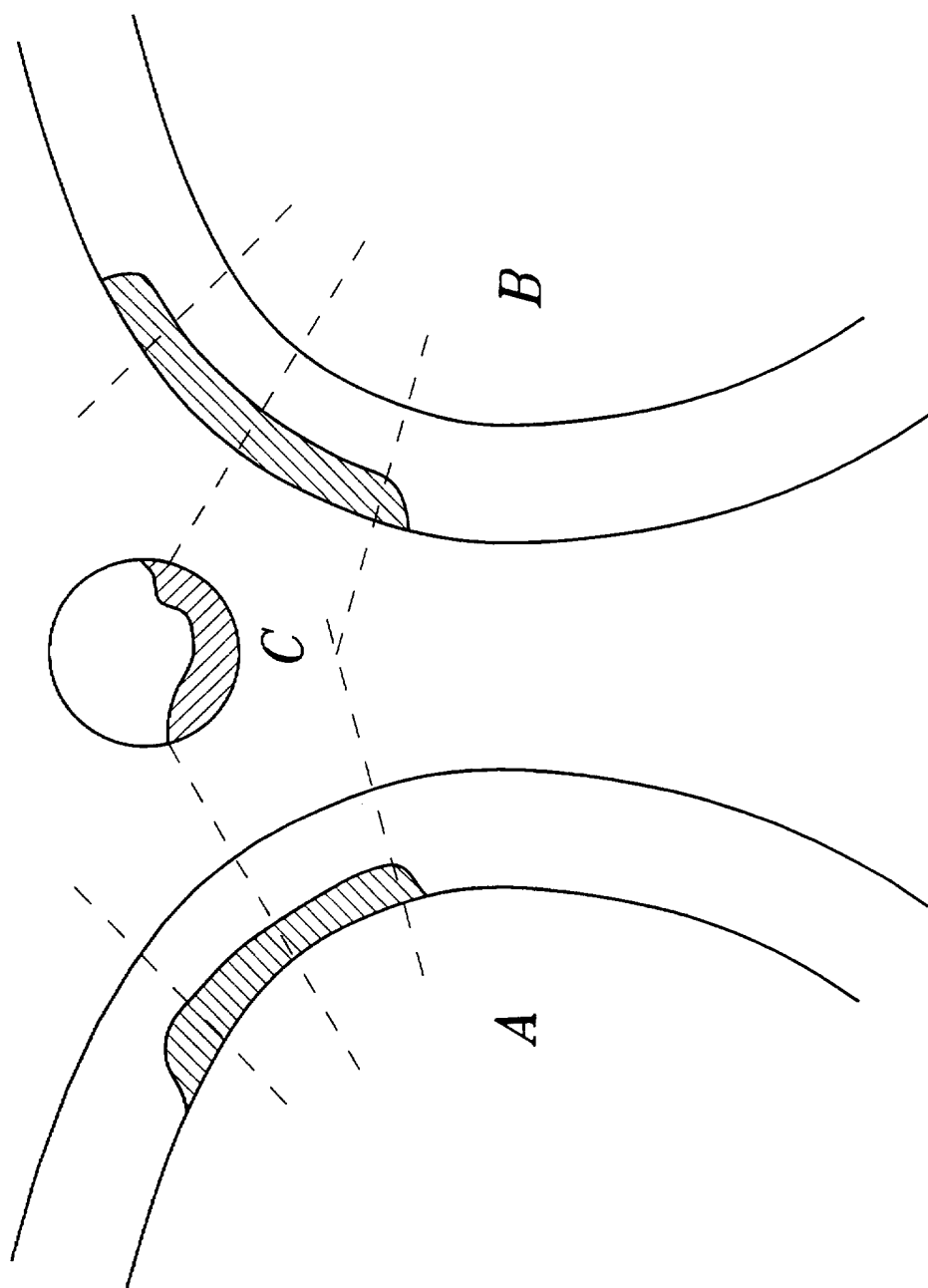
FIG. 8
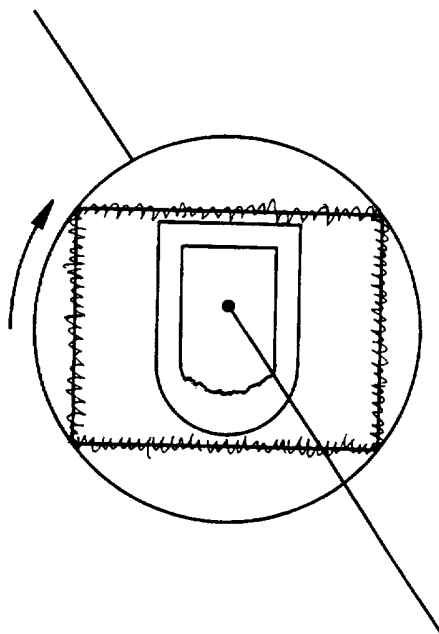
FIG. 9B

FIG. 9A

INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6   A61B8/12

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)
IPC 6   A61B   A61M

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 practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	COMPUTERS IN CARDIOLOGY, 10 - 13 September 1995, VIENNA (AT), pages 325-328, XP000646302 M. LABAN ET AL.: "ANGUS: A New Approach to Three-Dimensional Reconstruction of Coronary Vessels by Combined Use of Angiography and Intravascular Ultrasound" cited in the application see the whole document	1-14, 18-20
Y	US 5 345 938 A (M. NISHIKI ET AL.) 13 September 1994 see the whole document	1-14, 18-20
A	US 4 838 879 A (S. TANABE ET AL.) 13 June 1989 see abstract; figures 1-9	14-16

-/--

[X] Further documents are listed in the continuation of box C.	[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
30 May 1997	1 3. 06. 97

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INTERNATIONAL SEARCH REPORT

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	CIRCULATION, vol. 93, no. 3, 1 February 1996, pages 567-576, XP000646339 J.L. EVANS ET AL.: "Accurate Three-Dimensional Reconstruction of Intravascular Ultrasound Data" cited in the application see the whole document ---	1-14
A	US 5 353 798 A (W. SIEBEN) 11 October 1994 cited in the application see column 44, line 39 - column 46, line 29; figures 1-60 ---	1,14, 18-20
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