



US 20090196470A1

(19) **United States**

(12) **Patent Application Publication**

**Carl et al.**

(10) **Pub. No.: US 2009/0196470 A1**

(43) **Pub. Date: Aug. 6, 2009**

(54) **METHOD OF IDENTIFICATION OF AN ELEMENT IN TWO OR MORE IMAGES**

(30) **Foreign Application Priority Data**

Jun. 30, 2006 (DK) ..... PCT/DK2006/000387

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**Publication Classification**

(51) **Int. Cl. G06K 9/00 (2006.01)**

(52) **U.S. Cl. .... 382/128**

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(57) **ABSTRACT**

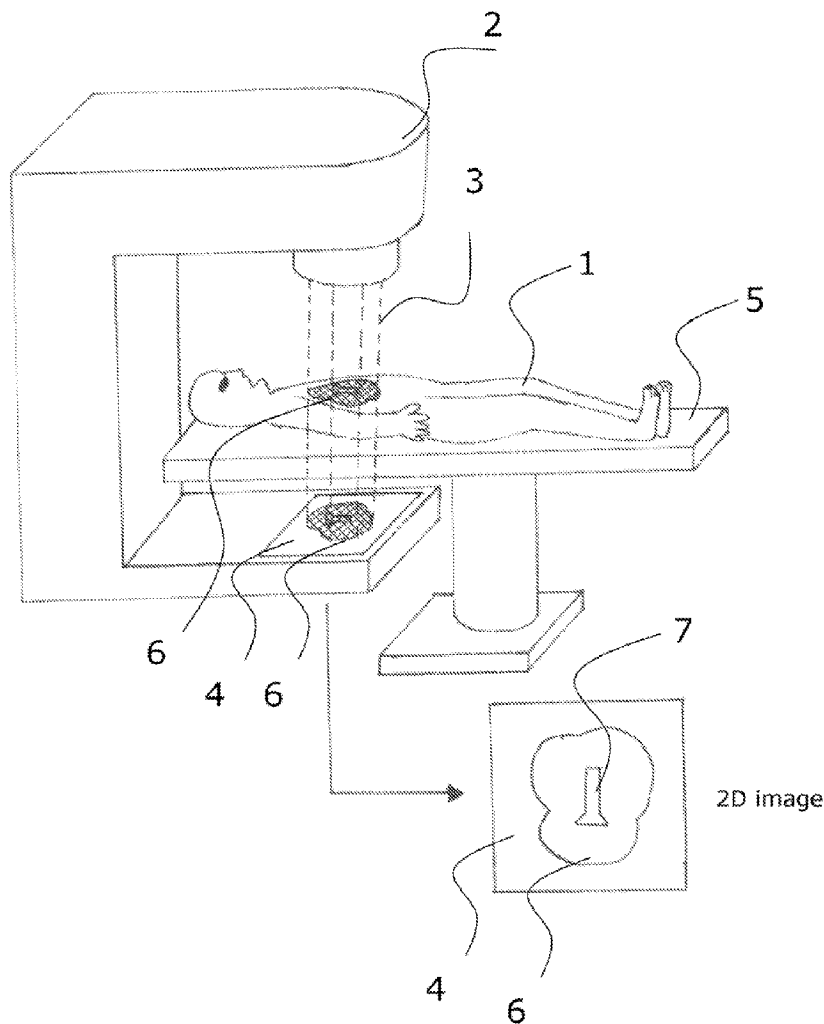
The present invention relates to a method and an apparatus for identification of an element in two or more images. The method comprises the steps of, identifying, in an image an integral three-dimensional element visible in the image, and identifying in a first image the three-dimensional element, identifying in a second image the three-dimensional element. Subsequently, collating is performed based on the first image and the second image and based on a determination of the position of the three-dimensional element in the first image and the position of the three-dimensional element in the second image. Thereby, a position and/or an extension in three dimensions of a bodily matter of interest within the human body or the animal body may be established.

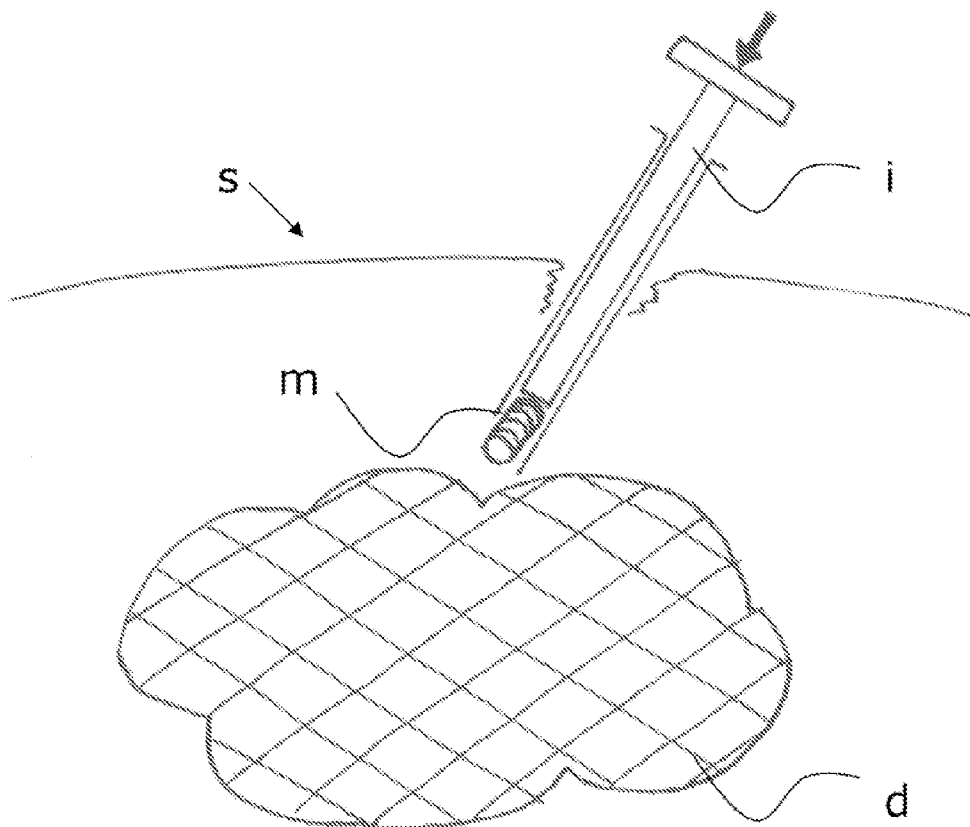
(21) Appl. No.: **12/306,900**

(22) PCT Filed: **Jun. 29, 2007**

(86) PCT No.: **PCT/DK2007/050081**

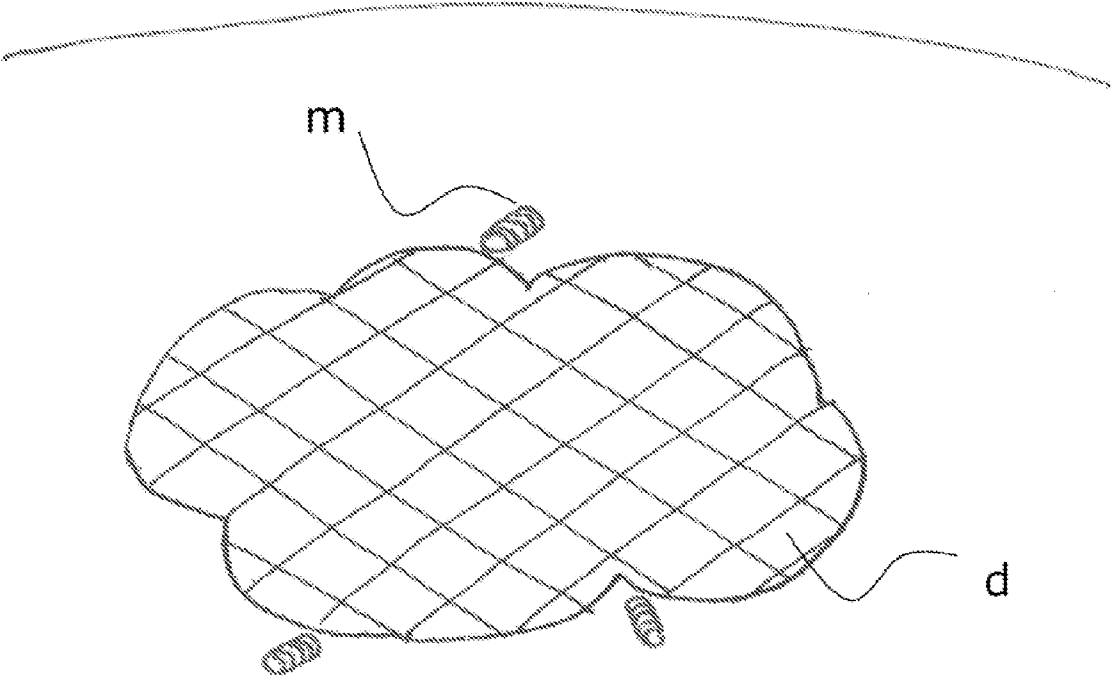
§ 371 (c)(1),  
(2), (4) Date: **Mar. 16, 2009**





PRIOR ART

Fig. 1



PRIOR ART

Fig. 2

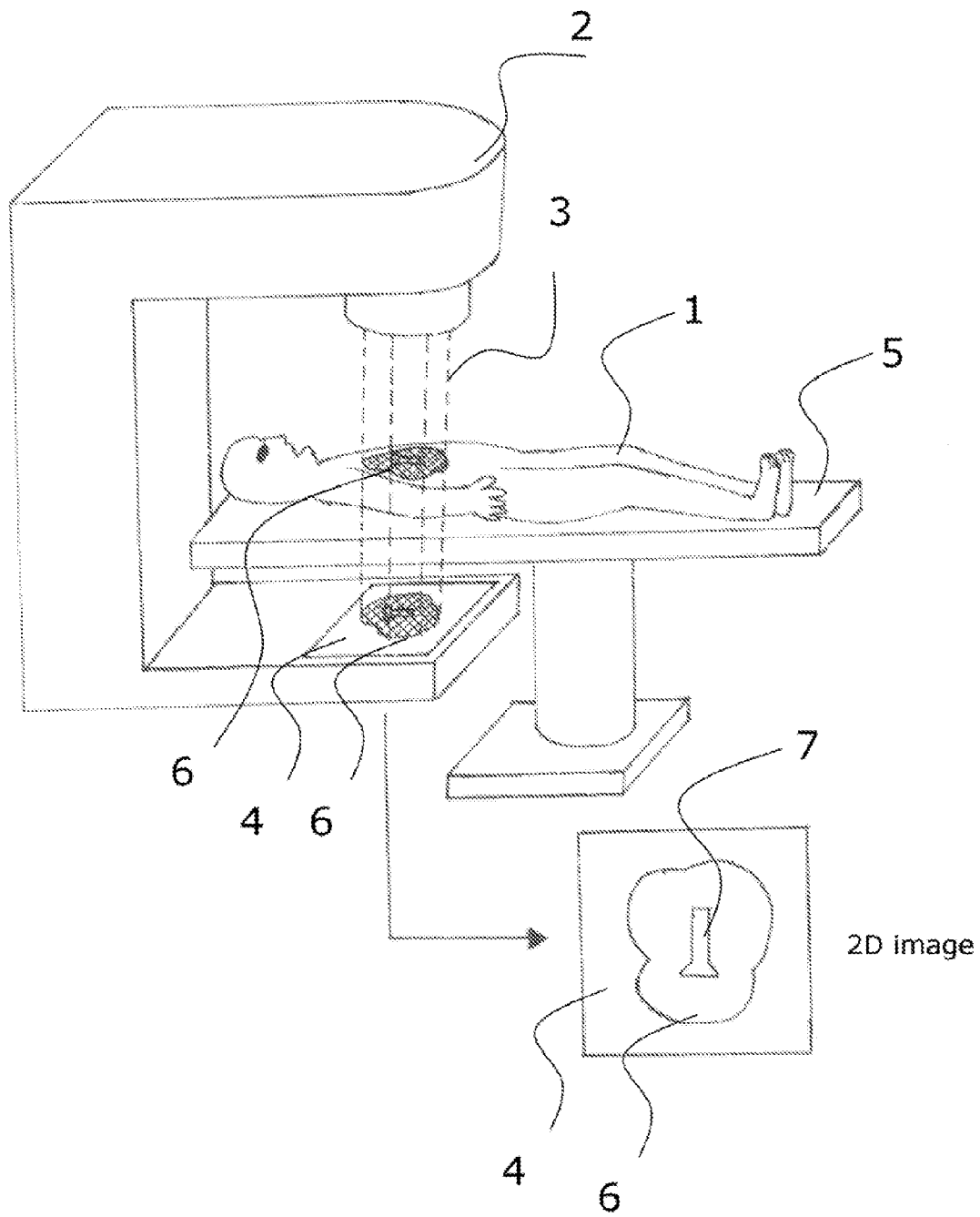


Fig. 3

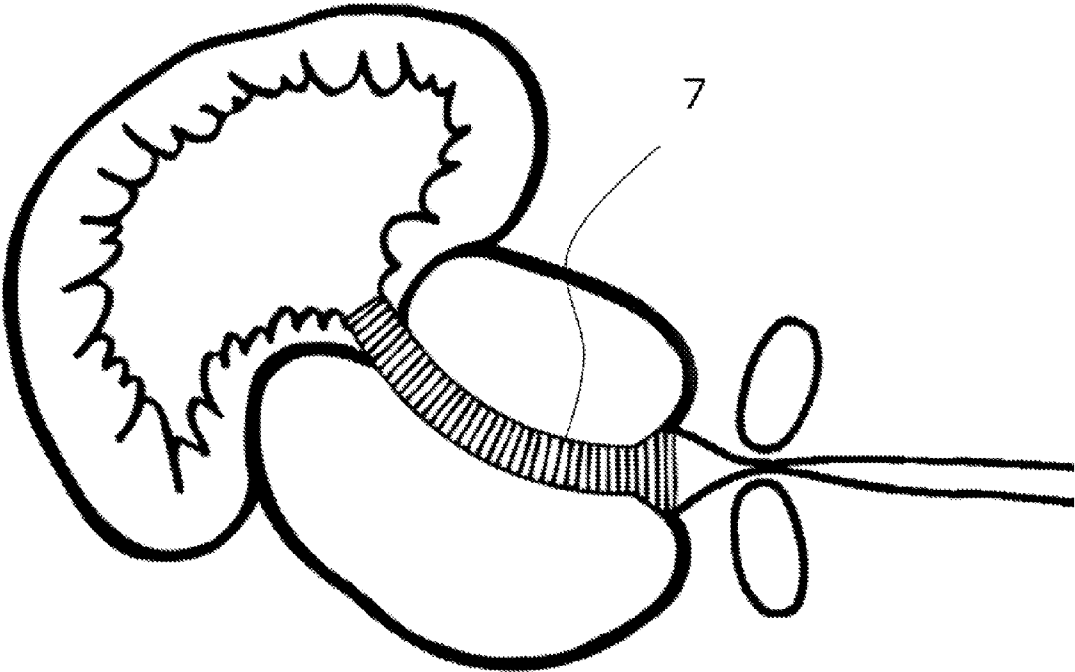


Fig. 4

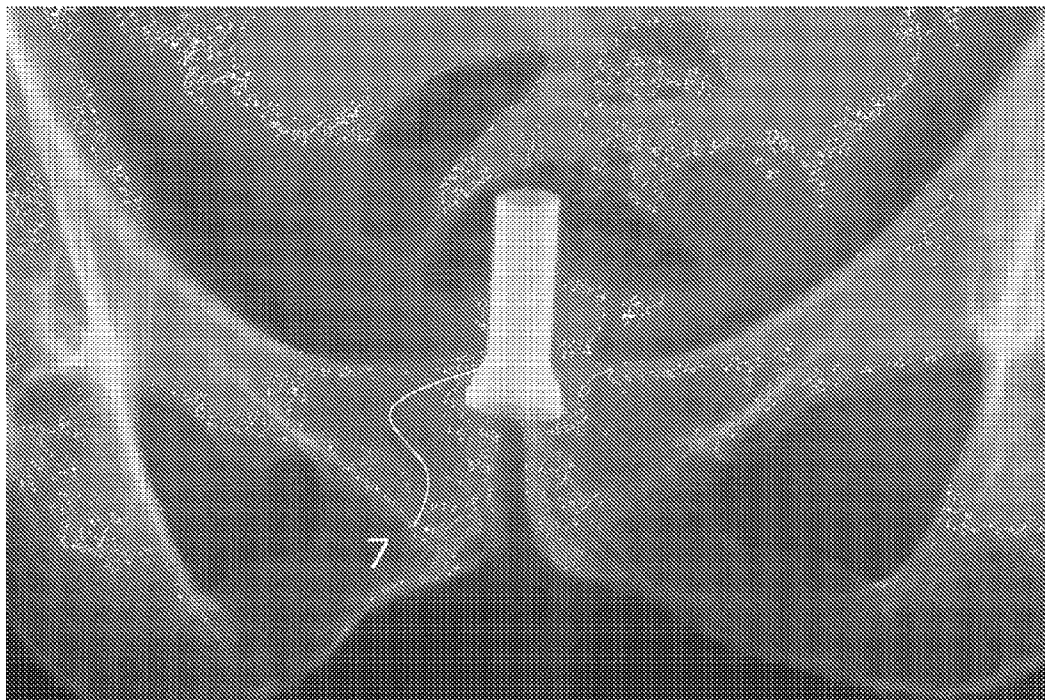


Fig. 5

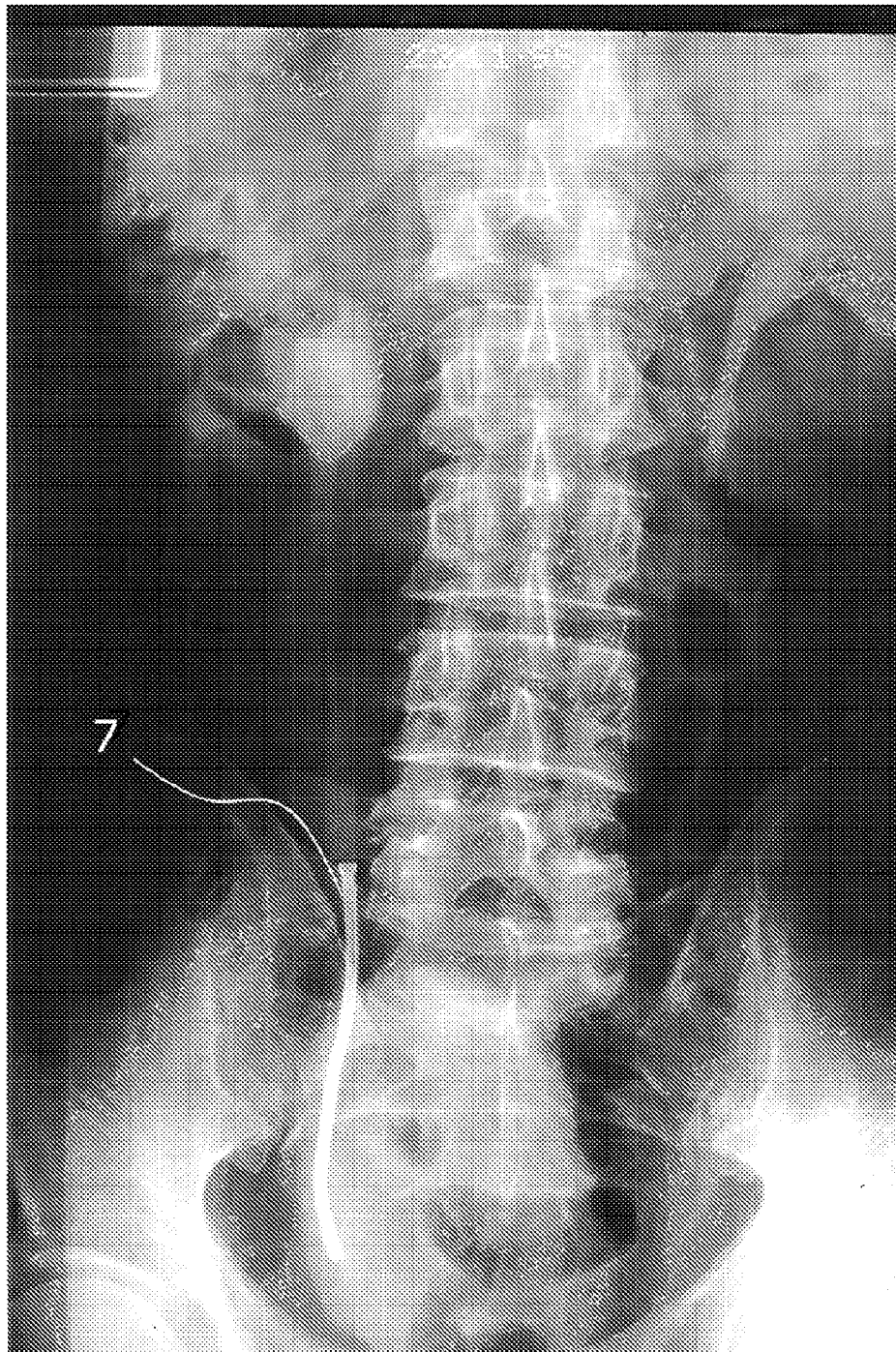


Fig. 6

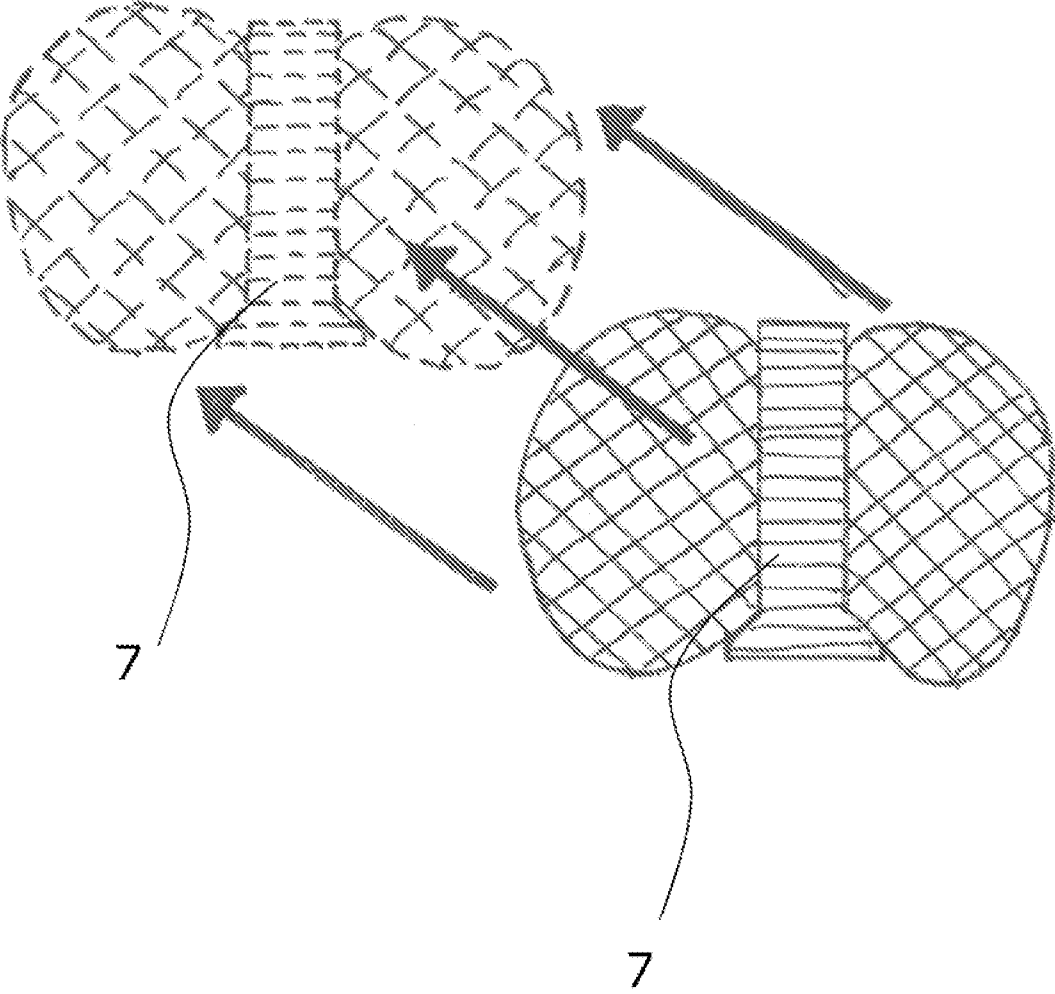


Fig. 7



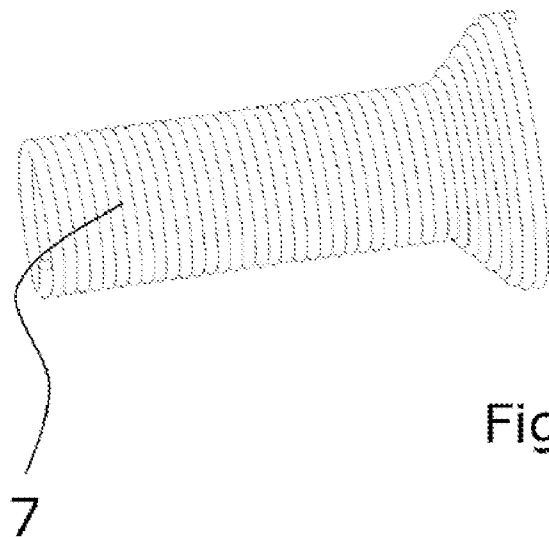


Fig. 8

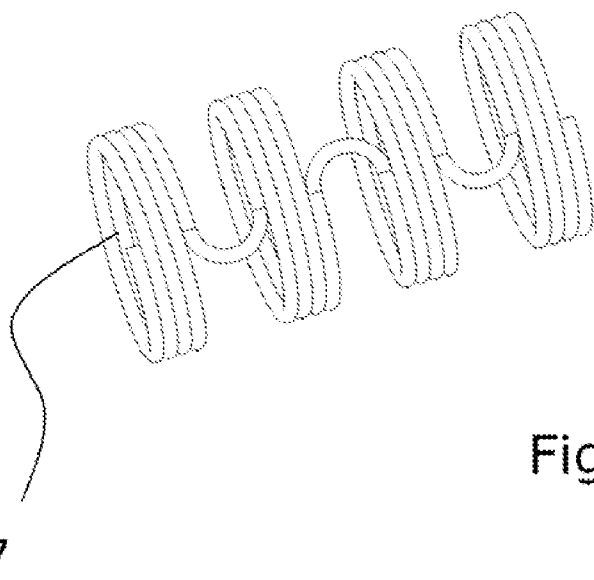


Fig. 9

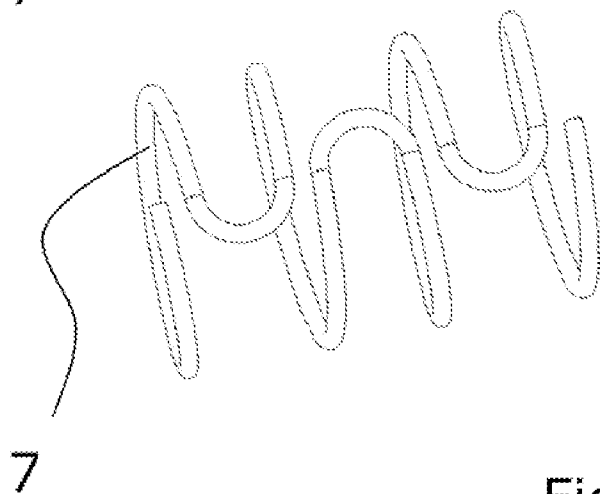


Fig. 10

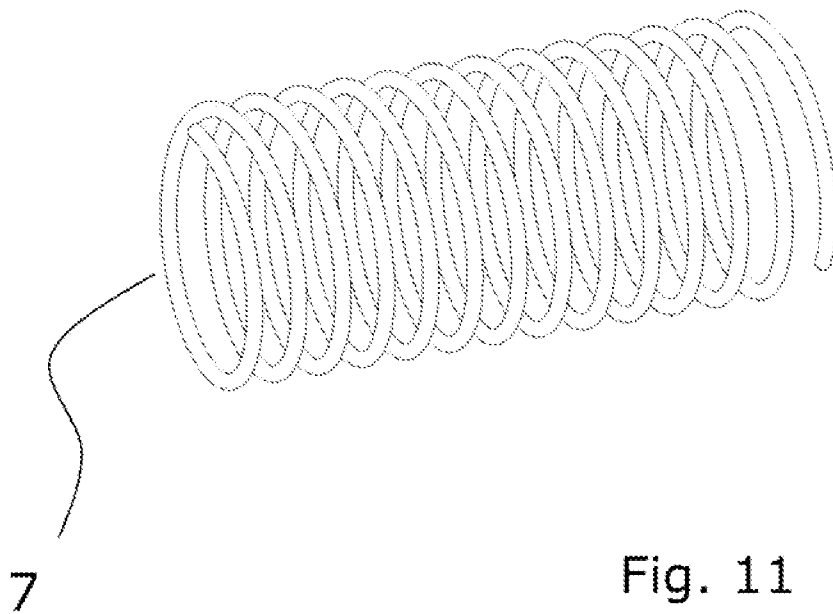


Fig. 11

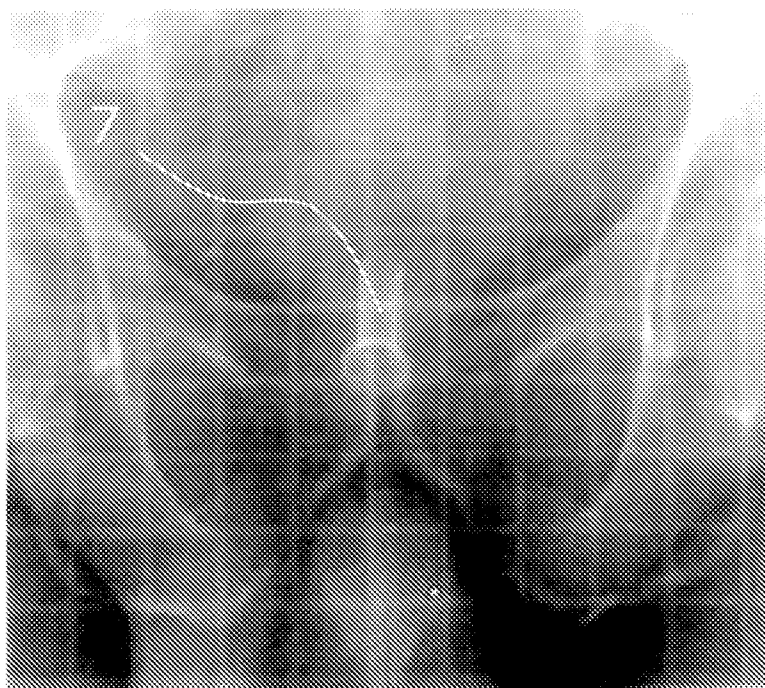


Fig. 12

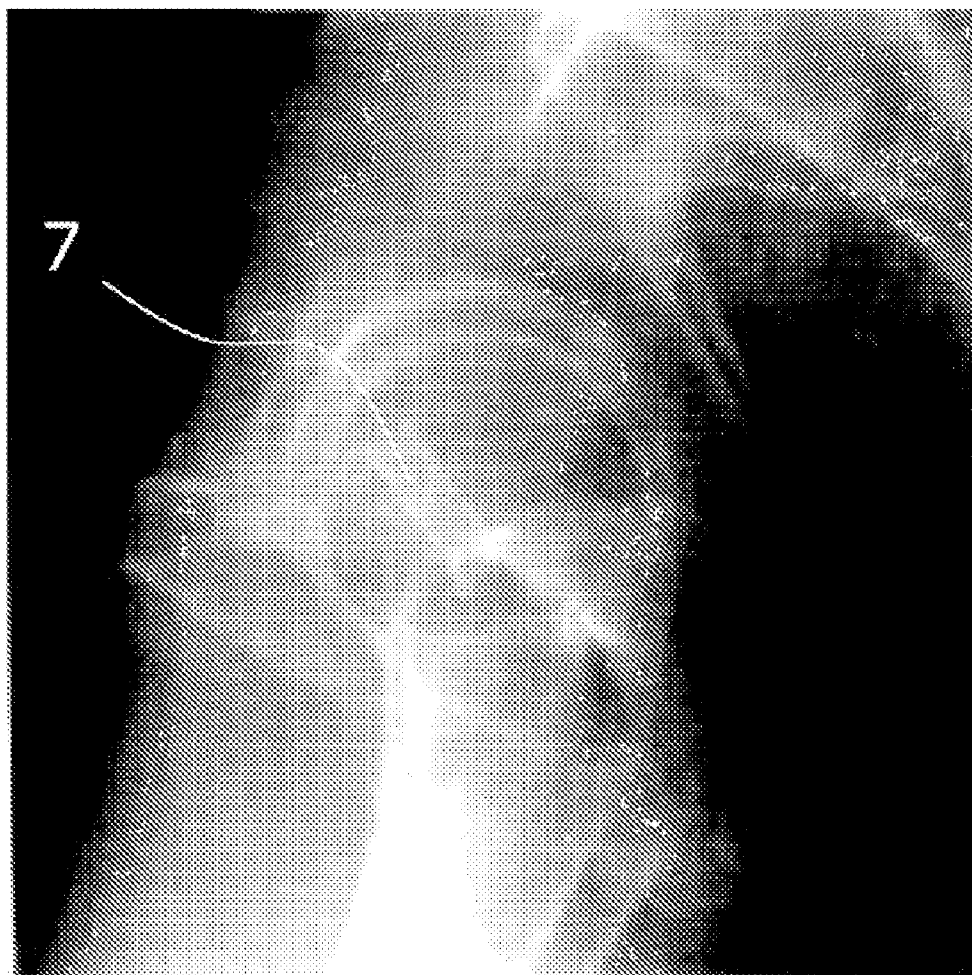


Fig. 13

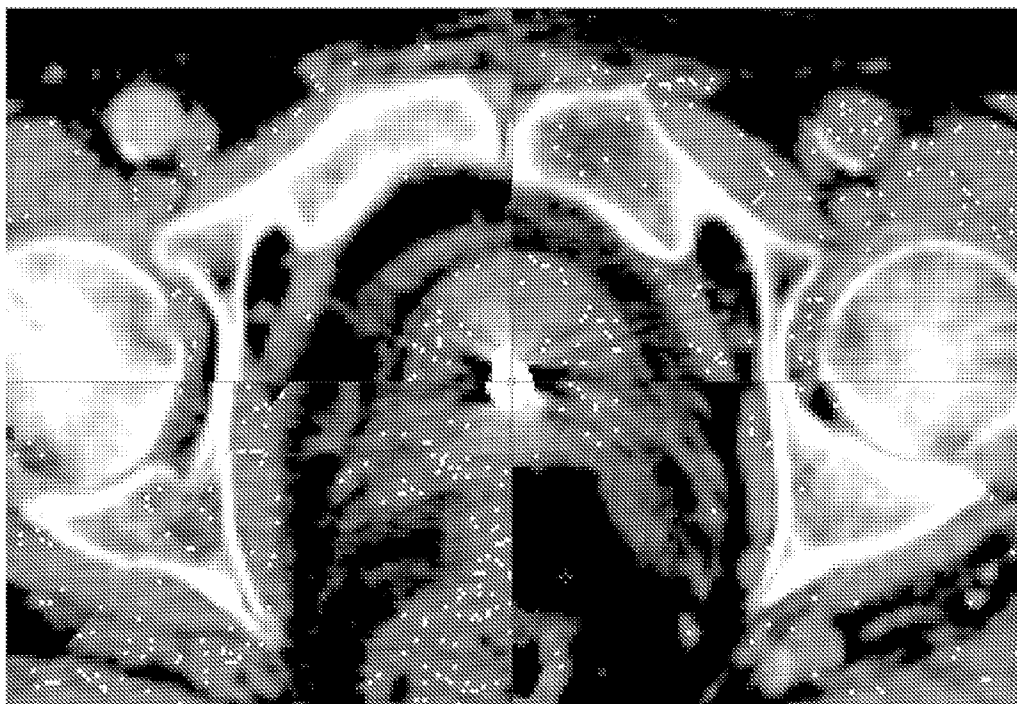


Fig. 14

## METHOD OF IDENTIFICATION OF AN ELEMENT IN TWO OR MORE IMAGES

### FIELD OF INVENTION

**[0001]** The present invention generally relates to a method for identifying an element common in two or more images and subsequently collating the two or more images based on the common element. The present invention specifically relates to a method for identifying an element being positioned in a human body or an animal body in relation to bodily matter such as a tissue or an organ or other bodily matter.

**[0002]** The invention may also relate to establishing a bodily parameter such as temperature, blood flow, nerve impulses or other bodily parameters of interest within the human body or the animal body. The bodily parameter is established based on identifying the element in relation to the bodily matter of interest.

### BACKGROUND

**[0003]** A problem associated with the prior art medical imaging techniques concerns the accurate selection and comparison of views of identical areas in images that have been obtained by imaging equipment at different times or by images obtained essentially at the same time using different image modalities, e.g., CT, MRI, SPECT, and PET, or by images obtained essentially at the same time using different set-up conditions. This problem has two aspects.

**[0004]** First, in order to relate the information in an image of the anatomy to the anatomy itself, it is necessary to establish a one-to-one mapping between points in the image and points on the anatomy. This is referred to as registering image space to physical space.

**[0005]** The second aspect concerns the registration of one image space to another image space. The goal of registering two arbitrarily oriented images is to align the coordinate systems of the two images such that any given point in the scanned anatomy is assigned identical addresses in both images. The calculation of the rigid body transformation necessary to align images requires knowledge of the movement and rotation of the anatomy in the images.

**[0006]** Calculation of the rigid body transformation of the anatomy for planar alignment of the coordinate systems of two-dimensional images requires knowledge of the coordinates of either at least two single points or a line in the images. Calculation of the rigid body transformation of the anatomy for three-dimensional alignment of the coordinate systems of three-dimensional images or multi angle two-dimensional images requires knowledge of the coordinates of either at least three single points, two lines in the images or a three-dimensional object in the images.

**[0007]** Single identifiable points marking identical locations in the images are called "fiducial points" or "fiducials," and the fiducials used are the geometric centres of markers, which are called "fiducial markers". These fiducials are used to correlate image space to physical space and to correlate one image space to another image space. The fiducial markers provide a constant frame of reference visible in a given imaging mode to make registration possible.

**[0008]** One problem extant in the field lies in the provision of fiducials capable of use with several imaging modalities. MRI and X-ray CT images are digital images, in which the images are formed point by point. These points are called picture elements, or pixels, and are associated with an inten-

sity of light emitted from a cathode ray tube, or are used to form an image on film. The array of lighted pixels enables the observer to view an image.

**[0009]** The manner in which the intensity of any given pixel is altered or modulated varies with the imaging modality employed. In X-ray CT, such modulation is a function primarily of the number of electrons per unit volume being scanned. In MR imaging, the parameters primarily influencing this modulation are the proton spin density and longitudinal and transverse relaxation times T1 and T2, which are also known as the spin-lattice and spin-spin relaxation times, respectively.

**[0010]** By using and combining different imaging modalities, one can benefit from the characteristics of the different modalities, facilitating some in-body objects being clearer and easier to identify in one image modality than in another and vice versa. Hereby improved identification of in-body objects and improved diagnosis is facilitated.

**[0011]** In constructing a fiducial marker, one must be aware that an agent that can be imaged under one imaging modality will not necessarily be imageable under another modality. And yet, the ability to image under both CT and MRI with a given marker would be especially useful, in that one would then be able to register images derived from different imaging modalities. For example, the capability to register CT and MR images would allow the integration of information concerning bony structure provided by a CT scan with the soft tissue anatomical information provided by an MRI scan. There remains a need for a fiducial marker that can be used to establish a known coordinate system under several imaging modalities, and which facilitates anatomical alignment of the different images.

**[0012]** A further problem in the field arises from the competing needs of accommodating patient comfort, which would tend to lead clinicians toward the minimization of marker size, for a less traumatic implantation process, with the desire of clinicians to use markers that are as bright and thus as large in the images as possible. Such brightness is desirable because it provides a strong signal that can be distinguished from noise inherent in the imaging process. The use of large-sized markers is also desirable so that the image of the marker occupies as many full pixels as possible. Increasing the number of full pixels occupied by the marker increases the accuracy with which the position of the marker can be determined, and the safety that the fiducial point can be clearly identified and is not mixed up with other points in the images.

**[0013]** Furthermore, the general technique of using fiducial markers requires the determination of the centroid of the marker; it is easier to compute the centroid for a large, bright marker than for a smaller, dimmer marker. On the other hand, the larger the marker of the prior art is, the more difficult it is for the patient to tolerate its presence for extended periods of time when the marker is buried in the tissue. There remains a need for a marker which can exploit the advantages presented by increased size that would also be tolerated by the patient during the period of its use. There is also a need for a small multi-modality marker that can be implanted into a patient and remain there for more extended periods of time, without harming the patient.

**[0014]** Furthermore there is a need for a single marker that can provide information on the coordinates of at least three points within the different images.

**[0015]** Such a more permanent fiducial marker would preferably be detectable by a non-invasive technique so that its position in physical space could be determined and its centroid computed even as it remains hidden from visual inspection beneath the patient's skin.

**[0016]** U.S. Pat. No. 6,333,971 describes an implantable fiducial marker having a sealed cavity for the introduction of an imaging agent that provides imaging capability in several modes, including Computed Tomographic imaging (CT) and Magnetic Resonance Imaging (MRI). The marker may be permanent, or it may be temporary and readily detachable from its anchor site. Combinations or agents imageable under CT scanning are combined with agents imageable under MRI scanning. The choice of imaging agents allows for the construction of a marker that is visible under both CT and MRI imaging modalities. Furthermore, by using a marker that comprises a solid outer portion and an aqueous inner portion, the marker can be located through the use of a non-invasive transcutaneous detection system, such as one employing ultrasound to detect the presence of the solid-liquid interface between the aqueous core and the solid outer portion. The use of solid metal is eschewed throughout. The presence of metal may cause unwanted artefacts and image distortion in the image, and may impede efforts to localize the marker.

**[0017]** Visicoil™, a product from Radiomed Corporation in the USA, consists in linear fiducial markers that are naturally visible by ultrasound, X-Ray, CT, MRI, and high-energy photons (portal images), allowing the physicians to implant the markers under one mode and later visualize them by another technique for treatment planning. Visicoil™ markers can be more easily recognized than the much larger point markers and with less confusion. Two or more Visicoil™ markers is needed for providing three-dimensional volume information. The Visicoil™ markers have to be implanted into the tissue of interest by invasive surgery and the Visicoil™ technique needs at least two markers for establishing an exact determination of a location of the tissue of interest. Thus, both the invasive surgery and the implantation of two or even more markers increase the risk of trauma to the patient.

**[0018]** One example of applications benefiting from alignment of different images is in relation to treatment of cancerous lesions in the human body irradiation of the disordered tissue, such as a tumor, is used in order to destroy the disordered tissue. The disordered tissue may be placed in all parts of the body. When the disordered tissue is positioned in some parts it may be difficult to irradiate without crucially damaging other essential parts of the body and in some cases the irradiation can cause irreversible damage.

**[0019]** Thus, the irradiation of the disordered tissue is restricted by the amount of irradiation, which healthy tissue may tolerate without being crucially or irreversibly damaged. This limitation of the irradiation is further increased by the fact that it may be difficult to precisely locate the disordered tissue and to determinate the extension of the disordered tissue inside the body.

**[0020]** Due to the fact that different diagnostic imaging technologies result in different parts and organs of the patient's body to be clearly identified, a combination of different imaging technologies such as CT, MR, PET, SPECT, X-ray, High-voltage X-ray is often used for localisation of the bodily matter of interest (e.g. a cancerous tumor being the target for irradiation. The different images might be merged in a fusion of two or more images using data processing equipment. By combining the different imaging technologies

a more accurate identification and localisation of a bodily matter of interest is possible, e.g. a cancerous tumor. In order to make the identification and localisation of the bodily matter of interest accurate, the images need to be aligned accurately near the bodily matter of interest.

**[0021]** A combination of different images, generated by different imaging technologies is for example used during the planning of radiation therapy. During the planning of radio therapy, the cancerous tumor is identified in diagnostic images, e.g. CT, MR, PET, SPECT, X-ray. Hereafter position and form of the tumor is localised and a profile of the irradiation to be given to the patient is generated, based on the form and position of the tumor.

**[0022]** Diagnostic images made with different imaging technologies and different apparatuses are often obtained with a time interval between the images, and with the patient repositioned on a different couch for each image. This results in different set-up conditions for each image. The different set-up conditions result in a difference between the actual positions of the bodily matter of interest inside the body of the patient in the different images, compared to visual objects in the images (bone structures, outer surface of the patient's body etc.), placed a distance from the bodily matter of interest. The difference between the positions of the bodily matter of interest in the different images can occur either by internal organ motion inside the patient's body and/or by inaccurate positioning of the patient under the image generating equipment.

**[0023]** Today, fusion between different diagnostic images is often aligned by using anatomic markers, which are visual in the different diagnostic images (bone structure, outer surface of the patient's body etc.). Those anatomic markers are often positioned a distance from the bodily matter of interest. Due to the fact that the bodily matter of interest will often have made a relative motion, compared to the anatomic markers positioned a distance away from the bodily matter of interest, an alignment of the different images based on the anatomical markers will result in inaccurate alignment of the images near the bodily matter of interest.

**[0024]** Alternatively fusion between the different diagnostic images can be aligned according to implanted fiducial markers or implanted line markers. Other factors which can lead to inaccurate alignment of the images are differences in the set-up conditions for the imaging equipment or the patient (e.g. the images are not obtained in exactly the same angle, and/or the image quality is not identical in the individual images (the image quality does often depend on the focal point).

**[0025]** A combination of different images can also be used for setting up treatment apparatuses, for example an irradiation equipment for external beam radio therapy of a cancerous tumor. The irradiation target is localised in at least one reference image during a planning session, prior to the treatment session. When starting a treatment session the treatment apparatus can be set up based on fusion between the reference image and an image obtained just before treatment or during treatment.

**[0026]** U.S. Pat. No. 5,853,366 describes a system to be used for radio therapy of a tumor. The location of the tumor is performed by inserting at least three markers in relevant positions around the periphery of the tumor. These markers are made from stainless steel capable of being detected in a conventional X-ray image of the body in order to position the irradiation source in relation to the tumor before irradiation of

the tumor. Each marker is depicted as one point in an X-ray image. These markers are inserted directly into the tissue surrounding the tumor and the markers are barbed or V-shaped in order to securely fasten the markers into the tissue thereby inhibit movement of the markers. Subsequently to positioning of the markers and irradiation of the tumor, the barbed markers have to be removed by invasive surgery.

**[0027]** WO 99/27839 discloses a system for positioning and repositioning of a portion of a patient's body with respect to a treatment or imaging machine including multiple cameras to view the body and the machine. Index markers placed externally on the patient's body, either light-emitting, passive, geometric shapes, or natural landmarks, are identified and located by the cameras in 3D space. Anatomical targets determined from image scanning can be located relative to reference positions associated with the treatment or diagnostic machine. Several forms of camera, index markers, methods and systems accommodate different clinical uses. X-ray imaging of the patient further refines anatomical target positioning relative to the treatment or diagnostic imaging reference point. Movements of the patient based on comparative analysis of imaging determined anatomical targets relative to reference points on treatment or diagnostic apparatus are controlled by the system and process.

**[0028]** WO 02/19908 discloses a method and an apparatus for compensating for breathing and other motions of the patient during treatment, the method comprising: generating images of the target region prior to the treatment; periodically generating positional data about the internal target region based on markers implanted in the patient's body; continuously generating positional data about external motion of the patient's body using one or more external sensors; and generating a correspondence between the position of the internal target region and the external sensors so that the treatment is directed towards the position of the target region of the patient based on the positional data of the external sensors. The target region's position is subsequently matched to the position of the target region in the preoperative images.

**[0029]** WO 02/100485 discloses a system and method for accurately locating and tracking the position of a target, such as a tumor or the like, within a body. In one embodiment, the system includes one or more excitable beacons positioned in or near the target, an external excitation source that remotely excites the beacons to produce an identifiable signal, and a plurality of sensors spaced apart in a known geometry relative to each other. A computer is coupled to the sensors and configured to use the beacon signals to identify a target isocenter within the target. The computer compares the position of the target isocenter with the location of the treatment isocenter. The computer also controls movement of the patient and a patient support device so the target isocenter is coincident with the treatment isocenter before and during radiation therapy.

**[0030]** Markers as described above are used to define the extent of a disordered tissue area, and/or to guide the treatment equipment, but still the whole area may be difficult to view in the image. For this reason and other reasons when planning irradiation of disordered tissue, the medical practitioner or the attending physician plans the irradiation by applying an irradiation margin in order to be sure that all of the disordered tissue area is irradiated. This margin results in some of the healthy tissue being deliberately irradiated and therefore the aforementioned crucial damages may occur.

Also, only fiducial markers are disclosed. A fiducial marker itself provides no possibility of identifying any rotation of the marker. Fiducial markers provide no possibility of localizing the disordered tissue without having at least two, and as disclosed, preferably three fiducial markers employed.

**[0031]** Further reasons for applying the irradiation margin is the inaccuracy in positioning the patient below the irradiation equipment, the inaccuracy of the resolution of the derived image of the disordered tissue and the fact that the internal organs may move over time. Such movement of the internal organs may be caused by respiration and/or by day-to-day movements. The use of implanted markers for guiding the treatment as described above can, to some extent, improve the accuracy of the positioning of the patient.

**[0032]** U.S. Pat. No. 6,307,914 discloses a moving body pursuit irradiating device comprising a linac for controlling the irradiation of a medical treatment beam to a tumor, and a tumor marker buried in the vicinity of the tumor, a first X-ray fluoroscope for picking up an image of said tumor marker from a first direction, and a second X-ray fluoroscope for picking up the image of said tumor marker from a second direction at the same time as said first X-ray fluoroscope, first and second recognition processing sections which execute template matching at a real time level at a predetermined frame rate by a shading normalization mutual correlation method for applying a template image of the tumor marker registered in advance to image information digitized by said first and second image input sections, and calculate first and second two-dimensional coordinates of said tumor marker, a central arithmetic processing section for calculating three-dimensional coordinates of said tumor marker from the first and second two-dimensional coordinates calculated by said first and second recognition processing sections; and an irradiating control section for controlling the irradiation of the medical treatment beam of said linac by said calculated three-dimensional coordinates of the tumor marker.

**[0033]** Implanted markers of prior art that is positioned in the body of the patient are buried in tissue and therefore require invasive surgery to be inserted in the body as well as further subsequent invasive surgery to be retracted from the body.

**[0034]** Diagnostic images made with different imaging technologies and with different medical imaging equipment can be derived with a time interval between the images, and with the patient repositioned on a different couch for each image. This results in different set-up conditions for each image. The different set-up conditions result in a difference between the actual position of the tissue of interest inside the body of the patient in the different images, compared to visually clear objects in the images, placed a distance from the tissue of interest, such as bone structures, outer surface of the patient's body etc. The difference between the positions of the tissue of interest in the different images can occur either by internal organ motion inside the patient's body and/or by inaccurate positioning of the patient below the medical imaging equipment.

**[0035]** A need exists however of an improved marker and a method for collating different images obtained by different imaging equipment, and/or obtained with a time interval between the images, and/or obtained with different set-up conditions for the images, in order to at least partly overcome the aforementioned disadvantages of the prior art relating to localizing the tissue of interest. An improved marker is a marker easy to detect and sufficiently precise to detect in

different imaging equipment. An improved marker may alternatively or additionally be a marker easy to implement into and/or easy to retract from the human or animal body.

#### SUMMARY OF THE INVENTION

**[0036]** An objective of the present invention is to provide a method for overcoming the disadvantages and drawbacks of the known methods and systems presented above.

**[0037]** These objectives and the advantages that will become evident from the following description of the invention are obtained by the following embodiments and aspects of the method according to the present invention by providing a method for identification of an element in two or more images, the method comprising the steps of,

**[0038]** identifying, in an image, at least one integral three-dimensional element visible in the image, said at least one integral three-dimensional element being in position in relation to a bodily matter of interest within a human body or an animal body, the method comprising the steps of:

**[0039]** identifying in a first image the three-dimensional element, visible in the first image,

**[0040]** identifying in a second image the three-dimensional element, visible in the second image,

**[0041]** collating the first image and the second image based on a determination of the position of the three-dimensional element in the first image and the position of the three-dimensional element in the second image, and

**[0042]** A method according to the invention, employing an improved marker, said marker possible being a single marker with at least three identifiable points, results in knowledge not hitherto obtainable about movement and/or rotation and/or change of shape and/or change of extension of the tissue or the organ of interest, preferably in three dimensions.

**[0043]** With the three-dimensional element being positioned and fixed in relation to a bodily matter of interest a mutual positional relationship between the three-dimensional element and the bodily matter of interest can be established. The knowledge about the position of the three-dimensional element in the image gives an exact knowledge of where the bodily matter of interest is positioned, because the bodily matter of interest and the three-dimensional element have been found to have a substantially fixed relationship and any possible movement of the bodily matter of interest results in corresponding movement of the three-dimensional element and vice versa. Images can be aligned according to the three-dimensional element and hereby also bodily matter of interest will be aligned in the images.

**[0044]** In the context of the present invention, bodily matter is to be construed as any matter relating to the body, e.g. any of the different body organs, body tissue including abnormal body tissue such as a tumor or body substances such as ascites, bile, blood, cerebrospinal fluid, lymph or urine, etc.

**[0045]** In the context of the present invention, tissue is defined as cells grouped together in the body to form tissues, i.e. a collection of similar cells that group together to perform a specialized function. Four primary tissue types are defined in the human body:

**[0046]** Epithelial tissue—The cells of epithelial tissue pack tightly together and form continuous sheets that serve as linings in different parts of the body. Epithelial tissue serves as membranes lining organs and helping to keep the body's organs separate, in place and protected. Some examples of

epithelial tissue are the outer layer of the skin, the inside of the mouth and stomach, the intestines and the tissue surrounding the body's organs, the respiratory epithelium and the endothelium of the various blood vessels.

**[0047]** Connective tissue—Generally speaking, connective tissue adds support and structure to the body. Most types of connective tissue contain fibrous strands of the protein collagen that add strength to connective tissue. Some examples of connective tissue include the inner layers of skin, tendons, ligaments, cartilage, bone and fat tissue. In addition to these forms of connective tissue, bone is also considered a form of connective tissue.

**[0048]** Muscle tissue—Muscle tissue is a specialized tissue that can contract. Muscle tissue contains the specialized proteins actin and myosin that slide past one another and allow movement. Examples of muscle tissue are contained in the muscles throughout the body.

**[0049]** Nerve tissue—Nerve tissue contains two types of cells: neurons and glial cells. Nerve tissue has the ability to generate and conduct electrical signals in the body. These electrical messages are managed by nerve tissue in the brain and transmitted down the spinal cord to the body.

**[0050]** In the context of the present invention, organs are defined as a structure containing at least two different types of tissue functioning together for a common purpose. The different body organs may be of interest imaging for the purpose of diagnosis and/or therapy and/or surgery. There are ten major organ systems in the human body:

**[0051]** Skeletal system: The skeletal system is providing support for the body, to protect internal organs and to provide attachment sites for the organs. Major skeletal system organs are bones including the skull, cartilage, tendons and ligaments.

**[0052]** Muscular system: The muscular system providing movement. Muscles work in pairs to move limbs and provide the organism with mobility. Muscles also control the movement of materials through some organs, such as the stomach and intestine, and the heart and circulatory system. Major muscular system organs are skeletal muscles and smooth muscles.

**[0053]** Circulatory system: The circulatory system is transporting nutrients, gases (such as oxygen and CO<sub>2</sub>), hormones and wastes through the body. Major circulatory system organs are the heart, blood vessels and the blood.

**[0054]** Nervous system: The nervous system is transmitting electrical signals through the body. The nervous system directs behaviour and movement and, along with the endocrine system, controls physiological processes such as digestion, circulation, etc. Major nervous system organs are the brain, the spinal cord and the peripheral nerves.

**[0055]** Respiratory system: The respiratory system is providing gas exchange between the blood and the environment. Primarily, oxygen is absorbed from the atmosphere into the body and carbon dioxide is expelled from the body. Major respiratory system organs are the nose, trachea and the lungs.

**[0056]** Digestive system: The digestive system is breaking down and absorbing nutrients that are necessary for growth and maintenance. Major digestive system organs are the mouth, esophagus, the stomach, small and large intestines.

**[0057]** Excretory system: The excretory system is filtering out cellular wastes, toxins and excess water or nutrients from the circulatory system. Major excretory system organs are the kidneys, ureters, the bladder and urethra.



**[0058]** Endocrine system: The endocrine system is transmitting chemical messages through the body. In conjunction with the nervous system, these chemical messages help control physiological processes such as nutrient absorption, growth, etc. Many glands exist in the body that secrete endocrine hormones. Among these, the major endocrine system organs are the hypothalamus, pituitary, thyroid, pancreas and adrenal glands.

**[0059]** Reproductive system: The reproductive system is producing cells that allow reproduction. In the male, sperm are created to inseminate egg cells produced in the female. Major female reproductive system organs are the ovaries, oviducts, the uterus, vagina and mammary glands. Major male reproductive system organs are the prostate, the testes, seminal vesicles and the penis.

**[0060]** Immune system: The immune system is destroying and removing invading microbes and viruses from the body. The lymphatic system also removes fat and excess fluids from the blood. Major immune system organs are lymph, lymph nodes and vessels, white blood cells, T- and B-cells.

**[0061]** According to a possible method according to the invention, the method further comprises a step of

**[0062]** establishing a position and/or establishing an extension of a bodily matter in the human body or the animal body, the establishing being based on collating the first image and the second image.

**[0063]** According to the present invention, each individual image may be a two dimensional projection image or a three-dimensional image, and wherein the image is derived and processed by medical imaging equipment.

**[0064]** According to the invention the steps of identifying the three-dimensional element and collating the images based on the determination of the position of the three-dimensional element in the images may be performed in more than two images.

**[0065]** According to the invention the steps of identifying the three-dimensional element and collating the images based on the determination of the position of the three-dimensional element in the images may be performed in images obtained by different imaging modalities.

**[0066]** According to the invention the steps of identifying the three-dimensional element and collating the images based on the determination of the position of the three-dimensional element in the images may be performed in images obtained with different set-up conditions (e.g. images obtained from different angles, or images obtained with a deliberate or an undeliberate movement of the patient and/or of the tissue of interest (and hereby a movement of the three-dimensional element) between the images).

**[0067]** According to the invention the steps of identifying the three-dimensional element and collating the images based on the determination of the position of the three-dimensional element in the images may be performed in images obtained with a time interval between the images being obtained, potentially resulting in different set-up conditions in the images, and/or movement of the tissue of interest (and hereby a movement of the three-dimensional element) within the human body or the animal body between the images.

**[0068]** Given a possibility to align different images more exactly than by the prior art methods, facilitates the possibility to track a development over time, within images obtained at different times. Tracking a development over time, within images obtained at different times, facilitates tracking of movement and/or growth/shrinking of body elements, in gen-

eral called bodily matter, for better diagnosis (e.g. tracking of the growth of a cancerous tumor or tracking of the movement of a cancerous tumor according to the patient's breathing cycle).

**[0069]** Examples of applications which might benefit from exact alignment of different images are:

**[0070]** Collating images (obtained by different imaging technologies and/or obtained in different planes/angles). Collating images (obtained by different imaging technologies and/or obtained in different planes/angles) by the method according to the invention, and incorporating use of a three-dimensional element as a marker, results in improved identification of bodily matter and the better identification results in a better diagnosis.

**[0071]** Possible use applications in relation to collating images by a method according to the invention may be the following non-exhaustive list of applications:

**[0072]** Reduction of inaccuracies due to set-up differences between the images

**[0073]** Identification of unwanted in-body elements (e.g. position and size of cancer tumors, position and size of encrustations or stone-formations, position and size of foreign bodies or one or more fetuses)

**[0074]** Planning of treatment and/or identification of treatment target (e.g. planning of irradiation treatment)

**[0075]** Identification and/or diagnosis of orthopaedic damages (bone fractures, joint fractures or joint dislocations)

**[0076]** Identification of possible obstructions of bodily lumens (e.g. urothelial obstructions due to encrustation or foreign bodies, cardiovascular obstructions due to encrustation, etc.)

**[0077]** Further examples of applications which might benefit from exact alignment of different images are:

**[0078]** Comparing images (obtained at different times. comparing a present image with a reference image). Comparing images by the method according to the invention, and incorporating use of a three-dimensional element as a marker, results in tracking of progress of movement and/or growth/shrinkage of a bodily matter of interest.

**[0079]** Possible use applications in relation to comparing images by a method according to the invention may be the following non-exhaustive list of applications:

**[0080]** Tracking of growth or shrinkage of a cancerous tumor.

**[0081]** Tracking of growth or shrinkage of a cardiovascular lumen.

**[0082]** Tracking movement of a foreign body, a parasite or the like.

**[0083]** Correction of inaccuracies due to set-up differences between obtaining the reference image and obtaining the present image.

**[0084]** Correction of inaccuracies due to internal body organ movements between obtaining the reference image and obtaining the present image.

**[0085]** Tracking internal body organ movements.

**[0086]** The correction of inaccuracies due to set-up differences and/or due to internal body organ movements, and/or the tracking of internal body organ movements may be established for different reasons, such as:

**[0087]** Controlling external treatment equipment according to linear movement and rotation of the treatment target (e.g. guiding an irradiation equipment).

**[0088]** According to a possible method step according to the invention, subsequent to establishing a position of a bodily matter of interest and/or establishing an extension of a bodily matter in the human body or the animal body, a bodily parameter is derived based on establishing the position and/or the extension of the bodily matter.

**[0089]** In the context of the present invention, bodily parameters are to be construed as any parameter related to the body, e.g. physiologic parameters such as temperature, bodily fluid parameters such as flow of ascites, bile, blood, cerebrospinal fluid, lymph or urine flow, bodily electrochemical parameters such as nerve impulses, etc.

**[0090]** Combination of different images, generated by different imaging technologies, and/or generated under different set-up conditions may be used during the planning of therapy or surgery. During the planning of therapy or surgery, a bodily matter of interest, such as an organ of interest, e.g. the prostate, or such as a tissue of interest, e.g. a cancerous tumor, or such as a substance of interest, e.g. urine, is identified in diagnostic images. Hereafter position and shape of the bodily matter is localised and the specifications of the therapy or surgery to be given to the patient is generated, based on the shape and/or position and or extension of the bodily matter.

**[0091]** Any inaccuracy of the identification of the bodily matter during the planning of therapy or surgery will result in inaccuracy during the treatment or surgery, resulting in a risk that the therapy or surgery does not effect the intended bodily matter of interest. Possibly, it may result in a traumatic effect of healthy matter and/or it may result in part of the unhealthy matter not being treated or not being properly handled during treatment.

**[0092]** By deriving at least a first image and a second image, and by collating the images by determining the position of the three-dimensional element, the three-dimensional element and hereby the bodily matter of interest will be identically positioned in the images. Thereby, the possible advantages of the first type of medical imaging equipment and the possible other or additional advantages of the second type of medical imaging equipment will be obtained at the one and same time in respect of the mutual positional relationship between the three-dimensional element and the bodily matter of interest. Additionally or alternatively inaccuracies in the alignment of the images resulting from different set-up conditions, when obtaining the images, may be compensated.

**[0093]** By using a three-dimensional element as marker being positioned inside, or at least in close vicinity of the bodily matter of interest, the images can be collated very accurately near the marker, and hereby near the bodily matter of interest. Hereby it is possible to collate the images accurately based on the position, in the images, of the three-dimensional element, hereby ensuring that the position and/or the shape and/or the extension of the bodily matter of interest, being positioned in an accurate position in relation to the three-dimensional element, is also determined accurately in the images.

**[0094]** By using a three-dimensional element as marker being positioned inside, or at least in close vicinity of the bodily matter of interest, it is furthermore possible to compensate for different image quality in the images. Often the image quality in one image is depending on the focal point of the image. By collating the images according to a three-dimensional element located inside or near the tissue of interest, improved compensation of different image quality in the

images is facilitated and/or improved compensation of different image quality in different parts of each individual image is facilitated.

**[0095]** Given the more accurate determination of the position and/or the shape and/or the extension of the bodily matter of interest in the different images of the different medical imaging equipment, a physicist and/or medical personnel will be able to identify and localise the bodily matter of interest, such as a cancerous tumor, very accurately.

**[0096]** Contrary hereto, when trying to compare images that are derived by different medical imaging equipment, according to prior art methods, the mutual positional relationship between a marker and the bodily matter of interest is not possible to establish accurately due to the fact of the marker, either not being present in the human or animal body, or the marker not being positioned in a position ensuring a constant mutual relationship between the position of the marker and the position of the bodily matter of interest.

**[0097]** By using a marker that is a three-dimensional element, such as a tubular, endoluminal prosthesis with a well known three-dimensional geometry, the collation of the different images can be guided by an automatic detection of the three-dimensional element in the different images, hereby making it possible to automatically guide the collation of the position, in the different images, of the three-dimensional element and thus of the bodily matter of interest.

**[0098]** If the dimensions of the three-dimensional element are known in advance, the dimensions of the three-dimensional element give an exact knowledge of how the three-dimensional element is positioned inside the body and perhaps is being rotated inside the body. By knowing the dimensions of the three-dimensional element in advance and by being able to detect the dimensions in an image, the exact position of the three-dimensional element inside the body may be calculated automatically. The knowledge about the position of the three-dimensional element established in the image gives also an exact knowledge of where the bodily matter of interest is positioned, because the bodily matter of interest and the three-dimensional element have a substantially fixed relationship and any possible movement of the bodily matter of interest results in corresponding movement of the three-dimensional element and vice versa.

**[0099]** Hereby, alignment of the images and of the bodily matter of interest depicted in the images may be performed accurately and automatically based on the position of the element even though the patient and/or the image equipment has been moved between the image sessions or has moved just before setting up the patient and the imaging equipment.

**[0100]** It is likewise possible during a treatment of the patient to adjust a treatment equipment so that the element and thereby the bodily matter of interest, such as a tumor, of the patient stays in focus of the treatment equipment.

**[0101]** By being able to adjust the treatment equipment based on the element, the treatment may be performed more precisely and the adjustment of the treatment equipment may be done automatically by a computer.

**[0102]** Additionally, the method according to the present invention may further comprise the steps of:

**[0103]** monitoring over time a possible movement of the three-dimensional element in relation to the images,

**[0104]** A monitoring over time of the movement of the three-dimensional element and hereby of the bodily matter of interest facilitates a constant alignment of images and/or a calculation of a cyclic movement of the bodily matter of

interest (e.g. due to respiration) and/or a constant equalizing of a treatment apparatus, whereby an improved treatment is possible. Such a tracking can be calculated and controlled by a computer.

**[0105]** The steps of identifying, establishing, monitoring and adjusting may be done automatically, and the monitoring step may be executed at an appropriate frequency, such as once every 3 seconds or less depending on the equipment available.

**[0106]** Monitoring of the movement of the three-dimensional element may according to the present invention be performed by producing up to 50 images per second, at least 2-50 images per second, at least 1 image per second, at least 12 images per minute or at least 2 images per minute depending on the medical imaging equipment, at least 2-50 images per second, at least 1 image per second, at least 12 images per minute or at least 2 images per minute.

**[0107]** By sampling as frequently as described, the possible movement of the three-dimensional element and thus of the bodily matter of interest it is possible to track the movement almost in real-time of the three-dimensional element and hereby of the bodily matter of interest.

**[0108]** Hereby, the possible movements of the body and/or of the element can be used to equalize continuous images by adjusting the images in response to the possible movement of the three-dimensional element. It is likewise possible during the continuous imaging to adjust the imaging equipment so that the three-dimensional element and thereby the bodily matter of interest stays in focus of the image. Furthermore, the adjustment of the images may be an adjustment of the position of the imaging equipment, of the couch on which the patient is placed, of the focal point of the images, and so forth.

**[0109]** Additionally, the possible movements of the body and/or of the element can be used to adjust a treatment equipment, e.g. an irradiation equipment, according to the tracking.

**[0110]** Movements to be tracked may be a forced movement, such as a tilting or a partial rotation of the patient during irradiation. The movement may also be a voluntary or involuntary movement by the patient. The voluntary movement may be the patient moving on the couch or walking around in the irradiation room and the involuntary movement may be movements due to motoric diseases such as Parkinson's Disease or Cerebral Palsy.

**[0111]** The three-dimensional element as a marker can be used for collating two or more diagnostic images used for identification, localisation and generation of a therapeutic or surgical scheme generated during the planning of the therapeutic or surgical specification scheme. Use of the same three-dimensional element for both performing the therapy or surgery according to the specification scheme and for collating images for planning of the specification scheme is feasible without any need for reinsertion or repositioning of the three-dimensional element.

**[0112]** The three-dimensional element as a marker can specifically be used for collating two or more diagnostic images used for identification, localisation and generation of an irradiation profile generated during the planning of radio therapy. Use of the same three-dimensional element for both guiding an external beam radio therapy equipment and for collating images for planning of the radiation therapy is feasible without any need for reinsertion or repositioning of the three-dimensional element.

**[0113]** According to an aspect of the present invention the three-dimensional element may be intended for positioning in

an existing natural cavity within the human or animal body, without being buried in tissue. By positioning the three-dimensional element in an existing natural body cavity, the risks related to potential tissue damages and the patient's sensation of the element may be eliminated or at least minimized compared to implantable markers being implanted into the patient's tissue.

**[0114]** Additionally, according to an aspect of the present invention insertion of the three-dimensional element may be performed through a natural opening of the body without at all or at least without substantially penetrating any tissue of the body. This way of inserting a three-dimensional element as a marker does not acquire invasive surgery, and thereby the risks related to such surgery is eliminated or at least minimized compared to implantable markers being inserted by invasion of skin surfaces and/or tissue.

**[0115]** Furthermore, according to an aspect of the method of the present invention a step may be employed of retracting the three-dimensional element through a natural opening of the body without at all or at least without substantially penetrating any tissue of the body. By retracting the three-dimensional element through the natural cavity or opening, the removal of the three-dimensional element is performed without invasive surgery and the risks related to such surgery is eliminated or at least minimized compared to implantable markers being inserted by invasion of skin surfaces and/or tissue.

**[0116]** The three-dimensional element, when inserted into a natural cavity, is therefore not damaging the surrounding tissue because the cavity is a natural opening of the body. The element is therefore not penetrating any tissue in order to be fastened inside the body. The three-dimensional element may be fastened by at least partly abutting the inside of the cavity in order for the three-dimensional element not to move inside the cavity.

**[0117]** The three-dimensional element may have different geometrical properties depending on the actual intended position of the three-dimensional element in the human or animal body. Additionally or alternatively, the three-dimensional element may have different physical properties depending on the actual intended use of the three-dimensional element in the human or animal body, apart from the use as a marker in different images. Possibilities of geometrical and physical properties are mentioned in the following.

**[0118]** Thus, the three-dimensional element may have a shape allowing passage of a liquid, gas or solid inside the cavity in which the three-dimensional element is positioned. Hereby the natural flow of liquid, gas, or solid inside the cavity is maintained, such as urine in the urethra and blood in the vein, or such as intestinal gas in the intestines and breath in the trachea or in the lungs, or such as solid faeces in the intestines, even though a therapy or surgery may cause some swelling of the bodily matter surrounding the cavity.

**[0119]** The three-dimensional element may be expandable towards the cavity from inside the cavity, when released in the cavity, for fixing the three-dimensional element in its position at a relative position according to the bodily matter of interest. Likewise, the natural flow of liquid, gas or solid is maintained inside the cavity, such as urine in the urethra and blood in the vein, or such as intestinal gas in the intestines and breath in the trachea or in the lungs, or such as solid faeces in the intestines, even though the therapy or surgery may cause some swelling of the bodily matter surrounding the cavity.

**[0120]** Furthermore, by expanding the cavity into which the at least one integral three-dimensional element is positioned, the three-dimensional element is firmly positioned inside the cavity without moving inside the cavity. Any other fastening means such as a barbed shape of the three-dimensional element is dispensable, and the element is easily removed without damaging the inside of the cavity.

**[0121]** The three-dimensional element may have a tubular shape allowing passage of a liquid, gas or solid inside the cavity in which the three-dimensional element is positioned. A tubular shape will maintain holding the cavity open also during the irradiation and the possible resulting subsequent swelling.

**[0122]** The three-dimensional element may be a tubular endoluminal prosthesis. The three-dimensional element may therefore already be positioned inside the body for another purpose such as for expanding a diminished urethra or ureter. The three-dimensional element will maintain holding the cavity open, also during a treatment session and the possible resulting subsequent swelling caused by the irradiation. The three-dimensional element is capable of staying in the cavity during a period of at least 30 days and is therefore capable of keeping the cavity open to permeation of liquids, gases or solids all during a treatment session even though the treatment is divided into periods of hours, days or weeks.

**[0123]** In respect of the at least one integral three-dimensional element being a substantially tubular endoluminal prosthesis, the three-dimensional element reduces the need for any additional catheters in order to hold the cavity in which the three-dimensional element is inserted, open to permeation of liquids, gases or solids.

**[0124]** The at least one integral three-dimensional element may in yet another aspect of the present invention be a helical coil of at least one wire. Hereby it is obtained that retraction of the three-dimensional element is possible through the natural cavity or opening through which it was inserted by pulling the wire.

**[0125]** The three-dimensional element may have a design enabling insertion and/or retraction of the three-dimensional element with conventional endoscopic equipment. The three-dimensional element may have a collapsible design, enabling a collapsed design when inserting the three-dimensional element in a cavity of the human or animal body, and enabling an expanded design when the three-dimensional element has been positioned in the cavity of the human or animal body.

**[0126]** In case the three-dimensional element is inserted into a bodily cavity, the cavity may have at least one surrounding wall, and the at least one integral three-dimensional element may, according to the invention, have a collapsible design when inserting the three-dimensional element, and said three-dimensional element may have a design being expandable towards the surrounding wall of the cavity, when being released in the cavity. The collapsible design reduces the impact on the inside wall of the natural cavity through which the insertion takes place. When being in the collapsed state, the element may have a substantially linear extension, and when being in the expanded state, the element will change from the possibly linear extension to the three-dimensional extension.

**[0127]** An apparatus may be provided in conjunction with the invention, said apparatus being capable of carrying out the method according to any of the aforementioned methods, said apparatus comprising means for identifying the three-dimensional element, means for establishing a preliminary position

of the three-dimensional element and/or a therapeutic or surgical equipment, means for monitoring a possible movement of the element and/or means for adjusting the therapeutic or surgical equipment or the human body or the animal body in response to the movement.

**[0128]** The means for identifying the three-dimensional element may, in one aspect, be a computer program for image-detection and means for establishing a preliminary position of the three-dimensional element may also be a computer program for image-detection.

**[0129]** The therapeutic or surgical equipment may be any conventional equipment for therapeutic or surgical treatment of bodily matter, such as irradiation equipment for treating a tumor. Means for monitoring a possible movement of the element may be a computer transmitting signals to the means for adjusting the therapeutic or surgical equipment such as an irradiation equipment or to the means for adjusting the human body or the animal body in response to the movement.

**[0130]** The three-dimensional element may be made of a biologically compatible material, such as polymers, biological material or metal, such as stainless steel, titanium, platinum, palladium, nickel-titanium and other alloys or combinations of any of these materials. By applying a three-dimensional element of such a biologically compatible material the three-dimensional element does not cause infection when being in the cavity of the human or animal body.

**[0131]** The three-dimensional element may be made of a shape memory alloy having a transition temperature with a one-way-memory effect at a temperature above body temperature. By applying a shape memory alloy the three-dimensional element is capable of expanding within the cavity.

**[0132]** In another aspect of the present invention the at least one integral three-dimensional element may be made of a shape memory alloy having a transition temperature above body temperature, preferably between 37° C. and 50° C. By using shape memory alloy having a transition temperature between 37° C. and 50° C., the surroundings inside the body is not scalded, which otherwise may give rise to an infection or to damaged bodily matter.

**[0133]** Body temperature is construed as the temperature of the body of the human or of the animal during the application of the method according to the invention. In most applications of the method, the body temperature of a human will be around 37° C.

**[0134]** The body temperature may however differentiate depending on whether it is a human body or an animal body. Some animals have lower normal body temperature than humans, and some animals have higher normal body temperature than humans.

**[0135]** Also, the body temperature may differentiate depending on the physical state of the human or the animal. The temperature may be higher due to fever if the human or the animal is suffering from illness causing fever, and the body temperature may be lower due to perhaps unstable blood flow, if the human or animal is newborn or is elderly, or if the human or the animal is suffering from illness causing an unstable blood flow.

**[0136]** By applying a shape memory alloy the three-dimensional element is capable of expanding within the cavity when heated to the transition temperature. Provided the transition temperature is about the normal body temperature of the human or animal body, the expanding is performed when the body has warmed up the element and this expansion of the three-dimensional element is performed without additional

applying of heat. In the case of a transition temperature in range above the body temperature the expanding is obtainable by heating the three-dimensional element e.g. by flushing of sterile water or the like fluids, having a temperature above the transition temperature.

[0137] Alternatively or additionally, the three-dimensional element may be made of a material being plastically deformable by hand at a temperature below body temperature, preferably at a temperature below 37° C., more preferred at a temperature below 20° C. and above 5° C. By using a material being plastically deformable by hand the three-dimensional element may be easily retracted by the manual force of a physician, and the three-dimensional element may easily be deformed to a smaller size during the retraction of the three-dimensional element.

[0138] Even in the alternative, the three-dimensional element may be made of a shape memory alloy being super elastic at body temperature.

[0139] The medical imaging equipment according to the aspect of the invention may be any one of the following imaging equipment: Magnetic Resonance scan (MR-scan), Nuclear Magnetic Resonance scan (NMR-scan), Magnetic Resonance Image scan (MRI-scan), Computerized Tomography scan (CT-scan), Cone Beam CT-scan, Positron Emission Tomography (PET), Single Positron Emission Computed Tomography (SPECT), Single Positron Emission Tomography (SPET), Image-Guided-Radiation-Therapy (IGRT, Ultrasound-scan, or X-ray, high-energy photons equipment or high voltage equipment.

[0140] The image may, according to the invention, be derived and processed by utilizing energy of an irradiation source for treatment. Thereby use of other equipment is no longer necessary and a substantial amount of cost and space in the irradiation room is saved.

[0141] In an additional aspect of the invention, the image may be derived and processed by utilizing energy of the treatment irradiation beam. Thus, use of other equipment is no longer necessary and a substantial amount of cost and space in the irradiation room is saved.

[0142] Medical marker elements may be delivered to a target bodily matter such as a body organ or a body tissue via a marker element delivery system. The marker element delivery system may be an elongated device that is brought through to body vessels or other body cavities or in proximity to target organs or tissue. Once the marker element is in position, the marker element delivery system is retracted, while the marker element stays in place. The marker element delivery system may be specially designed depending different parameters such as the shape of the marker element and/or the body organ and/or the body tissue or the body cavity, into which the marker is to positioned and/or on a possible body opening through which the marker element delivery system is to be inserted and retracted. Use of such marker element delivery system allows medical personnel to perform marker positioning in a fast and non-invasive manner.

[0143] Possible applications where collating of two or more diagnostic images with a three-dimensional marker could be advantageous are the following non-exhaustive applications:

[0144] Planning of external radio therapy treatment, i.e. by a beam apparatus or other medical applications where there is an effect of some bodily matter such as tissue and/or a body part being easier to detect in one type of images than in another type of image.

[0145] Planning of internal radio therapy treatment including brachytherapy or other medical applications where there is an effect of some bodily matter such as tissue and/or body parts being easier to detect in one type of images than in another type of image.

[0146] Follow-up on anatomic changes on a patient's anatomy, e.g. growth or shrinking of a certain bodily matter such as a tissue of interest, e.g. a cancer tumor or other foreign body, or such as a bodily organ of interest, e.g. the liver or other more or less vital body organs, or such as bodily parameters e.g. nerve impulses from certain parts of the brain.

[0147] Follow-up during treatment, surgery or diagnosis of e.g. internal movement of certain bodily matter such as a tissue of interest, e.g. a cancer tumor or other foreign body, or such as a bodily organ of interest, e.g. the liver or other more or less vital body organ, or such as a bodily parameter of interest, e.g. nerve impulses to and from certain part of the brain.

[0148] Investigation of respiratory movement and/or rhythm, e.g. for the use of possible gating of a treatment session.

[0149] Guidance of external treatment equipment, e.g. an irradiation equipment, by tracking of internal body organ movements and/or correction of inaccuracies due to set-up differences, when obtaining the images.

[0150] The method according to the invention may be used in conjunction with a method for guiding a treatment equipment located outside a human body or outside an animal body. In the following an external beam radio therapy equipment is used as an example. The method could, however, be used for other types of treatment equipments. Said method of guiding comprising the steps of:

[0151] identifying, in an image, at least one integral three-dimensional element visible in the image, said at least one integral three-dimensional element being in position in a cavity of the human body or the animal body,

[0152] establishing, in the image, a preliminary position of the at least one integral three-dimensional element visible in the image in relation to a reference,

[0153] establishing a preliminary position of the irradiation equipment in relation to the reference,

[0154] adjusting the irradiation equipment in relation to the reference in response to the position of the at least one integral three-dimensional element in relation to the reference.

[0155] During the step of identifying, in an image, at least one integral three-dimensional element visible in the image, the at least one integral three-dimensional element is in position. Prior to identifying, in an image, at least one integral three-dimensional element visible in the image, an additional step may be inserting the at least one integral three-dimensional element into a cavity of the human body or the animal body.

[0156] By identifying the position of the at least one integral three-dimensional element in relation to the position of the disordered tissue, the position of the disordered tissue may then be established based on establishing the position of the three-dimensional element. This is advantageous due to the fact that the disordered tissue is not identifiable in all kinds of images, in which the three-dimensional element is identifiable. By being able to establish the position of the three-dimensional element in a two dimensional image, the exact

position of the disordered tissue may be established due to the fact that the element and the disordered tissue moves simultaneously in relation to the human or animal body.

**[0157]** The dimensions of the three-dimensional element are known in advance and based on the two-dimensional image of the three-dimensional element the dimensions give an exact knowledge of how the three-dimensional element is positioned inside the body and perhaps is being rotated inside the body. By knowing the dimensions of the three-dimensional element in advance and by being able to detect the dimensions in an image, the exact position of the three-dimensional element inside the body may be calculated. The knowledge about the position of the three-dimensional element established in the image gives an exact knowledge of where the disordered tissue is positioned, because the disordered tissue and the three-dimensional element have been found to have a substantially fixed relationship and any possible movement of the disordered tissue results in corresponding movement of the three-dimensional element and vice versa.

**[0158]** Hereby, positioning of the disordered tissue may be performed accurately based on the position of the element even though the patient has been moved between the examination room and the irradiation room or has moved just before setting up the patient and the treatment equipment for irradiation. It is likewise possible during the irradiation of the patient to adjust the equipment so that the element and thereby the disordered tissue, such as a tumor, of the patient stays in focus of the irradiation equipment.

**[0159]** By being able to adjust the irradiation equipment based on the element, the irradiation may be performed more precisely and the adjusting of the irradiation equipment may be done automatically by a computer.

**[0160]** Additionally, by being able to irradiate more precisely, it is possible to subject the patient to a higher total dose of irradiation without damaging tissue surrounding the disordered tissue and as a result it is possible to subject the patient to irradiation more times with the same refractory doses in order to more effectively eliminate the disordered tissue, or to subject the patient to irradiation fewer times with higher refractory doses in to more effectively eliminate the disordered tissue, without damaging healthy tissue.

**[0161]** Additionally, the method according to the present invention may further be used in conjunction with a method for adjusting an irradiation equipment located outside a human body or outside an animal body, said method comprising the steps of:

**[0162]** monitoring a possible movement of the three-dimensional element in relation to the irradiation equipment,

**[0163]** adjusting the irradiation equipment in response to the possible movement of the three-dimensional element.

**[0164]** Hereby, the aforementioned inaccuracies are increasingly diminished in that the possible movements of the body and/or of the element is equalized by adjusting the irradiation equipment in response to the possible movement of the at least one integral three-dimensional element. It is likewise possible during the irradiation to adjust the equipment so that the three-dimensional element and thereby the disordered tissue, such as a tumor, of the patient stays in focus of the irradiation equipment. Furthermore, the adjustment of the irradiation equipment may be an adjustment of the position of the irradiation equipment, of the couch on which the

patient is placed, of the power of the irradiation source, of the focal point of the beam, of the intensity of the irradiation beam, of movement of plates or a shield changing the shape of the irradiation beam, and so forth.

**[0165]** Additionally, the adjusting of the irradiation equipment may furthermore be a deflection or a focusing of the irradiation beam in relation to any movements during irradiation. Such movement may be a forced movement, such as a tilting or a partial rotation of the patient during irradiation. The movement may also be a voluntary or involuntary movement by the patient. The voluntary movement may be the patient moving on the couch or walking around in the irradiation room and the involuntary movement may be movements due to motoric diseases such as Parkinson's Disease or Cerebral Palsy.

**[0166]** The advantages of being able to adjust the irradiation equipment during irradiation reside in the possibility of irradiating the body from different angles. Thereby, the disadvantage of irradiating possibly healthy tissue surrounding the disordered tissue is minimized. Furthermore, the adjustment may be performed so that irradiation of certain critical healthy tissue is avoided. The adjustment of the irradiation equipment may also be a limitation of the total dose of irradiation from a certain angle in order to avoid exceeding the irradiation limit of healthy tissue being irradiated from that certain angle.

**[0167]** The steps of identifying, establishing, monitoring and adjusting may be done automatically, and the monitoring step may be executed at an appropriate frequency, such as once every 3 seconds or less depending on the equipment available.

**[0168]** According to the present invention in general, and not only related to guiding of irradiation equipment, different aspects and advantages are disclosed in the following:

**[0169]** In one aspect, a reference may be a previous image of the three-dimensional element having been inserted into the cavity of the body. Such a previous image may conveniently be the image in which the bodily matter of interest, such as a tumor, was detected and the position and/or shape of the bodily matter of interest were established during a pre-examination of the patient.

**[0170]** In another aspect, the previous image of the at least one integral three-dimensional element may also be the last image derived of the three-dimensional element or the image derived for setting up the patient before therapy or surgery.

**[0171]** Additionally, according to an aspect of the present invention insertion of the three-dimensional element may be performed through a natural opening of the body without at all or at least without substantially penetrating any tissue of the body. This way of inserting a three-dimensional element as a marker does not acquire invasive surgery, and thereby the risks related to such surgery is eliminated or at least minimized.

**[0172]** Furthermore, according to an aspect of the method of the present invention a step may be employed of retracting the three-dimensional element through a natural opening of the body without at all or at least without substantially penetrating any tissue of the body. By retracting the three-dimensional element through the natural cavity or opening, the removal of the three-dimensional element is performed without invasive surgery and the risks of contamination related to such surgery is eliminated or at least minimized.

**[0173]** The three-dimensional element, when inserted into a natural cavity, is therefore not damaging the surrounding

tissue because the cavity is a natural opening of the body. The element is therefore not penetrating any tissue in order to be fastened inside the body. The three-dimensional element is fastened by at least partly abutting the inside of the cavity in order for the three-dimensional element not to move inside the cavity.

**[0174]** Advantageously, when the invention is used in conjunction with a method for adjusting a therapeutic or surgical equipment such as an irradiation equipment located outside a human body or outside an animal body, monitoring and adjusting of the therapeutic or surgical equipment such as the irradiation equipment may be performed during therapeutic or surgical treatment such as irradiation of the bodily matter, e.g. a disordered tissue such as the tumor.

**[0175]** In another aspect of the present invention the at least one integral three-dimensional element may be a substantially tubular endoluminal prosthesis.

**[0176]** Additionally, possible monitoring of the movement of the at least one integral three-dimensional element may according to the present invention be performed by producing up to 50 images per second, at least 2-50 images per second, at least 1 image per second, at least 12 images per minute or at least 2 images per minute depending on the medical imaging equipment, at least 2-50 images per second, at least 1 image per second, at least 12 images per minute or at least 2 images per minute.

**[0177]** By sampling as frequently as described, the possible movement of the three-dimensional element and thus of the disordered tissue may be equalized almost instantly and the method is performed almost continuously, whereby the aforementioned damage of healthy tissue can be substantially decreased.

**[0178]** According to the present invention, each individual image may be a two dimensional projection image or a three-dimensional image, and wherein the image is derived and processed by medical imaging equipment.

**[0179]** Furthermore, when the invention is used in conjunction with a method for adjusting an irradiation equipment located outside a human body or outside an animal body, the patient is not unnecessarily irradiated. When the dose of irradiation is calculated, the irradiation of the patient, in order to produce images to establish the extension of the disordered tissue, such as a tumor, is included. The dose is calculated so that the surrounding healthy tissue is not un-recoverably damaged. The irradiation of the patient is thereby used in order to treat the patient in the correct area and not just for producing examination images.

**[0180]** By using the same equipment as for irradiation of a disordered tissue, time is saved for changing equipment back and forth when an image has to be derived.

**[0181]** When the invention is used in conjunction with a method for adjusting an irradiation equipment located outside a human body or outside an animal body, the image may be derived and processed by utilizing electric energy from an energy source for producing electric power for the irradiation source.

**[0182]** The at least one integral three-dimensional element may have a design enabling insertion and/or retraction of the three-dimensional element with conventional endoscopic equipment. By being able to use conventional endoscopic equipment during insertion and/or retraction of the three-dimensional element, costs of additional equipment is saved and the time in changing between utilizations of different

equipment during the insertion or retraction of the three-dimensional element is decreased.

**[0183]** In case the three-dimensional element is inserted into a bodily cavity, the cavity may have at least one surrounding wall, and the at least one integral three-dimensional element may, according to the invention, have a collapsible design when inserting the three-dimensional element, and said three-dimensional element may have a design being expandable towards the surrounding wall of the cavity, when being released in the cavity. The collapsible design reduces the impact on the inside wall of the natural cavity through which the insertion takes place. When being in the collapsed state, the element may have a substantially linear extension, and when being in the expanded state, the element will change from the possibly linear extension to the three-dimensional extension.

**[0184]** An apparatus may be provided in conjunction with the invention, said apparatus being capable of carrying out the method according to any of the aforementioned methods, said apparatus comprising means for identifying the three-dimensional element, means for establishing a preliminary position of the three-dimensional element and a therapeutic or surgical equipment, means for monitoring a possible movement of the element and means for adjusting the therapeutic or surgical equipment or the human body or the animal body in response to the movement.

**[0185]** The means for identifying the three-dimensional element may, in one aspect, be a computer program for image-detection and means for establishing a preliminary position of the three-dimensional element may also be a computer program for image-detection.

**[0186]** The therapeutic or surgical equipment may be any conventional equipment for therapeutic or surgical treatment of bodily matter, such as irradiation equipment for treating a tumor. Means for monitoring a possible movement of the element may be a computer transmitting signals to the means for adjusting the therapeutic or surgical equipment such as an irradiation equipment or the human body or the animal body in response to the movement.

**[0187]** Medical marker elements may delivered to a target bodily matter such as a body organ or a body tissue via a marker element delivery system. The marker element delivery system may be an elongated device that is brought through to body vessels or other body cavities or in proximity to target organs or tissue. Once the marker element is in position, the marker element delivery system is retracted, while the marker element stays in place. The marker element delivery system may be specially designed depending different parameters such as the shape of the marker element and/or the body organ and/or the body tissue or the body cavity, into which the marker is to be positioned and/or on a possible body opening through which the marker element delivery system is to be inserted and retracted. Use of such marker element delivery system allows medical personnel to perform marker positioning in a fast and non-invasive manner.

#### BRIEF DESCRIPTION OF THE DRAWINGS

**[0188]** In the following, the present invention will be described with reference to the accompanying drawings, in which:

**[0189]** FIG. 1 shows a prior art marker being inserted by surgery through the tissue of a human body,

**[0190]** FIG. 2 shows three prior art markers which have been inserted into the tissue surrounding a tumor,

[0191] FIG. 3 shows a human body lying on a couch below a therapeutic or surgical equipment, in the embodiment shown an irradiation equipment,

[0192] FIG. 4 shows a three-dimensional element having been inserted into the natural cavity a urethra of a male,

[0193] FIG. 5 shows an X-ray image of a three-dimensional element as shown in FIG. 4,

[0194] FIG. 6 shows an X-ray image of another three-dimensional element,

[0195] FIG. 7 shows a three-dimensional element having been inserted into the natural cavity a urethra of a male,

[0196] FIG. 8 shows an example of a three-dimensional element,

[0197] FIGS. 9, 10 and 11 show other examples of a three-dimensional element,

[0198] FIGS. 12 and 13 show an example of three-dimensional element in an image derived from a mega voltage equipment, and

[0199] FIG. 14 shows an amalgamation of images having the three-dimensional element in the center and derived by CT-scan.

[0200] The drawings are schematically and shown for the purpose of illustration.

[0201] FIG. 1 shows the insertion of prior art markers m through the skin by use of invasive surgery, the insertion being done in order to locate the disordered tissue d, such as a tumor, in an image derived for positioning the irradiation of the tumor d. When inserted as shown in FIG. 2, the three or more markers m are positioned in relation to the irradiation equipment, and the irradiation source is turned on for a period of time. Subsequently to the time period of irradiation, the irradiation is interrupted. The irradiation of the tumor d may be continued when a period of at least a few days has lapsed so that the surrounding healthy tissue may withstand a new irradiation. During the time period of irradiation, the irradiation equipment is at no time adjusted in order to compensate for any movement of the tumor during this irradiation.

[0202] The prior art markers in shown FIGS. 1 and 2 may move considerably within the body between two irradiation periods in which case more markers may have to be inserted.

#### DESCRIPTION OF THE PRESENT INVENTION

[0203] Given a possibility to collate, align and compare different images more exactly than by the prior art methods, facilitates the possibility to combine different images, being derived by different imaging equipments, possibly being derived by different imaging modalities, and to track a development over time, within images obtained at different times. Combination of images being derived by different imaging equipments, possibly being derived by different imaging modalities, facilitates improved identification of a bodily matter of interest, e.g. identification of a cancerous tissue to be irradiated with an external beam radio therapy equipment. Tracking a development over time, within images obtained at different times, facilitates tracking of movement and/or growth/shrinking of bodily matter for better diagnosis, e.g. tracking of the growth of a cancerous tumor or tracking of the movement of a cancerous tumor according to the patient's breathing cycle.

[0204] In the following description of the invention, identification of a cancerous tumor, planning of the specifications of the irradiation treatment to be delivered to the cancerous

tumor, and, tracking a movement of the cancerous tumor will be used as one of several examples, where the present invention may be employed.

[0205] Possible other use applications in relation to collating images by the method according to the invention may be the following non-exhaustive list of applications:

[0206] Reduction of inaccuracies due to set-up differences between the images. In one example such as therapy by irradiation, inaccuracies may result in difficulties in only radiating the target tissue or in difficulties in controlling the intensity of irradiation. In an example of diagnosis, inaccuracies may result in difficulties in performing a medically safe diagnosis or in performing a sufficiently fast diagnosis. In an example of surgery, inaccuracies may result in difficulties in performing complicated surgery or in performing surgery within a narrow space.

[0207] Identification of unwanted in-body elements, e.g. position and size of cancer tumors, position and size of encrustations or stone-formations, position and size of foreign bodies.

[0208] Planning of treatment and/or identification of treatment target, e.g. planning of irradiation treatment, or identification of treatment target during diagnosis, or planning of surgery process during a surgery based on perhaps different images from different angles.

[0209] Identification and/or diagnosis of orthopaedic damages (bone fractures, joint fractures or joint dislocations), e.g. identification of small bone fractures within the body, or diagnosis of correct treatment of fractures or dislocations of physically complicated joints.

[0210] Identification of possible obstructions of bodily lumens, e.g. urothelial obstructions due to encrustation or foreign bodies, cardiovascular obstructions due to encrustation, etc.

[0211] Possible use applications in relation to comparing images by a method according to the invention may be the following non-exhaustive list of applications:

[0212] Tracking of growth or shrinkage of a bodily matter such as tracking non-wanted growth of cancerous tumor or tracking of intended shrinkage of a cancerous tumor during irradiation therapy, or tracking of non-wanted further shrinkage of cirrhosis of the liver, or tracking of intended growth of internal body organs such as a treated cirrhosis of the liver.

[0213] Tracking of growth or shrinkage of a cardiovascular lumen such as tracking of non-wanted stenosis shrinkage of blood vessels or tracking of intended growth of a stenosis of a blood vessel during therapy, or tracking of non-wanted further shrinkage of urethra, or tracking of intended growth of ventricles of the heart or volume of the lungs.

[0214] Tracking movement of a foreign body, a parasite or the like such as tracking of non-wanted biliary calculus or tracking or tracking of intestinal parasites like worms.

[0215] Correction of inaccuracies due to set-up differences between obtaining the reference image and obtaining the present image such as inaccuracies occurring between different times of treatment, where an outside element such as a patient bed is used as reference or such as inaccuracies occurring between on reference image of a first imaging equipment and another reference image of a second imaging equipment.



[0216] Correction of inaccuracies due to internal body organ movements between obtaining the reference image and obtaining the present image such as internal body organs moving during inhalation and exhalation or such as internal body organs having moved between one point of time imaging the body organ and a later point of time imaging the body organ.

[0217] In the following description of the invention, identification of a cancerous tumor, planning of the specifications of the irradiation treatment to be delivered to the cancerous tumor, and, tracking a movement of the cancerous tumor will be used as one of several examples, where the present invention may be employed. In the following, planning of irradiation treatment will be used as one example among all the examples mentioned above and among further examples of application, which the skilled person may envisage as applications of the method according to the invention.

[0218] In the following, a tumor 6 will be used as an example of disordered tissue. However, other types of disordered tissue, other than tumors, may also be treated during guiding of the irradiation equipment when employing an equipment guidance method as described. Also, other bodily matters of interest than disordered tissue may be subject to treatment by therapy or surgery during operation of therapeutic or surgical equipment when employing an equipment operating method, such as the irradiation guiding as described.

[0219] As mentioned, in the following, the invention will be described with reference to a cancerous tumor as example of bodily matter of interest. However, as previously mentioned, in the context of the present invention, bodily matter is to be construed as any matter relating to the body, e.g. body organs such as the prostate, body tissue such as a tumor or body substances such as urine, etc. Also, the invention is not limited to bodily matter, but may also be applied in relation to bodily parameters. As previously mentioned, in the context of the present invention, bodily parameters are to be construed as any parameter related to the body, e.g. physiologic parameters such temperature, bodily fluid parameters such as urine flow, bodily electrochemical parameters such as nerve impulses, etc.

[0220] Furthermore, as mentioned, in the following, the invention will be described with reference to irradiation and irradiation equipment as example of a method and an equipment of treatment. However, as previously mentioned, in the context of the present invention, treatment may also be other types of therapeutic treatment or may be surgical treatment, such as therapeutic treatment by brachy therapy, treatment of blood vessels or other vessels for the flow of bodily gas, liquid or solids etc. Possible types of surgical treatment may be insertion of irradiating agents for use in brachy therapy, insertions of surgical equipment for biopsy, insertion of surgical equipment for fertilisation treatment, guiding of surgical equipment during a surgery in any parts of the body etc.

[0221] Accordingly, the specific example of a cancerous tumor as a bodily matter of interest, and the specific example of irradiation as a method of treatment by therapy or surgery, and the specific example of irradiation equipment as an equipment for treatment by therapy or surgery is not to be construed as limiting the scope of protection according to the claims.

[0222] When a patient 1 has been given the diagnosis of having cancer, the cancer is often positioned inside the body of the patient in the form of disordered bodily matter, namely disordered tissue 6, such as a tumor 6, as shown in FIG. 3. The

disordered tissue may result in a disordered organ such as the prostate. If the patient is intended for having treatment by irradiation therapy, a step of planning the specifications of the irradiation to be delivered is often performed. The planning of the specifications of the irradiation to be given is often based on images depicting the bodily matter within and around the cancerous tumor.

[0223] One important part of planning the specifications of the irradiation to be given is to define the form of the target for the irradiation to be delivered. The target of the irradiation profile to be delivered will often contain both the tissue being identified as the cancerous tumor, and a margin surrounding the tissue being identified as the cancerous tumor, applied to compensate for any inaccuracies in the identification of the cancerous tumor in the planning images, and to compensate for any inaccuracies in the actual delivery of the irradiation treatment, e.g. any inaccuracies involved in positioning an irradiation equipment and a patient exactly as planned before starting a treatment session.

[0224] Any limitation of the inaccuracies in the identification of the cancerous tumor and any limitation of the inaccuracies involved in exact positioning of the irradiation equipment and/or of the patient facilitates a possibility to decrease the margin for compensation of these inaccuracies, and hereby such limitations of the inaccuracies may facilitate improved treatment with the potential of less side effects for the patient.

[0225] The image 4 for planning of the specifications of the irradiation to be given is investigated, and the tumor 6 is located in the image 4 before the actual treatment of the patient 1. A series of images 4 may be derived in order to establish the extension of the tumor 6. In one aspect of the present invention, the position of the three-dimensional element 7 is determined by producing a series of images 4 using as an example MR-scanning techniques or X-ray CT-scanning techniques. When establishing the extent of the tumor and if no element is already positioned in the body of the patient 1, a three-dimensional element 7, being suitable as a marker of the tumor 6, is inserted into the patient 1 before obtaining the images. In other situations, when establishing the extent of the tumor, an element, being suitable as a marker of the tumor 6, is already positioned in the body of the patient 1. The three-dimensional element is inserted or is in position within a certain distance from the tumor 6 to be treated or inside the volume to be treated. When irradiating a tumor 6 inside the prostate, the three-dimensional element 7 is often positioned inside the prostatic urethra and is therefore in immediate vicinity of the area 6 to be treated as shown in FIGS. 4, 5, 6, 7, 12, 13 and 14.

[0226] When having the three-dimensional element inserted in the patient, in a position within the cancerous tumor, or in a position near the cancerous tumor, and the three-dimensional element is known to be located and fixed in a position within the patient's body which moves in a mutual relationship with the cancer tumor, the three-dimensional element can be used for collating multiple diagnostic images intended for identifying the treatment target, and for planning the specifications of the irradiation.

[0227] Some imaging types are known to provide different information of different types of bodily matter. Therefore some tissue material (e.g. the cancerous tissue) may be easier to detect in a MR-image, but other crucial information about the surrounding bodily matter may be easier to detect in an X-ray CT-image, and vice versa. Therefore an improved plan

of the specifications for the irradiation may be generated based on a fusion of images from different imaging types, e.g. by collating MR-images and X-ray CT-images.

[0228] A known problem resulting from the prior art methods is however, that an exact alignment of the different types of images is often very difficult to generate, since the set-up conditions of the imaging equipments and/or the patient is not exactly identical when obtaining the different images. Furthermore it may be difficult to clearly detect identical points, lines, areas or volumes in all the different images, due to the different quality and characteristics of the different imaging types.

[0229] With the three-dimensional element inserted in the patient prior to obtaining the images, the three-dimensional element, with its characteristics of being clearly detectable in all types of images, can be used as a marker for alignment of the coordinate systems of the individual images, so that the different images are accurately aligned according to the three-dimensional element, possibly in three dimensions. Since the three-dimensional element is known to be positioned and fixed in a position within the patient's body in a mutual relationship with the bodily matter of interest, an alignment of the three-dimensional element in the images will also result in an alignment of the bodily matter of interest in the images.

[0230] The collation of the images based on the three-dimensional element will be accurate even though the images are obtained under different set-up conditions of the imaging equipments and/or of the patient, and even though the images might be obtained with a time interval between the obtaining of the images, and even though the images may have different picture quality.

[0231] The collation of the images used for planning the specifications of the irradiation may be performed automatically, guided by a computer, based on the known geometry of the three-dimensional element.

[0232] In one aspect of the present invention, the pre-treatment planning images may be stored as a reference for the later irradiation session. In the pre-treatment planning images the position of the three-dimensional element 7 is identified, and the position of the three-dimensional element relative to the cancerous tumor is stored for later referencing during the actual irradiation session. A reference position within the pre-treatment images could be set for example as a point in the middle of the three-dimensional element 7.

[0233] When starting the actual irradiation treatment session the irradiation equipment and/or the patient may be guided to its intended position, according to the plan of the specifications for the irradiation, by obtaining a new image of any imaging type, and based on a collation of this image and the pre-treatment planning images, based on the position of the three-dimensional element. When collating this just-before-treatment-image and the pre-treatment planning images the information about the difference between the position and the difference between the rotation of the three-dimensional in the just-before-treatment-image and the pre-treatment planning images gives the information needed to compensate for inaccuracies in the set-up of the irradiation equipment and/or the patient's position.

[0234] By deriving additional images during the actual irradiation session a similar guiding of the irradiation equipment and/or the patient's position may be performed during the actual irradiation session, based on the collation of the images according to the position of the three-dimensional element in each individual image. Hereby it becomes possible to com-

pensate for any movements of the irradiation equipment or the patient or internal organ movements within the patient's body, etc. that may occur during the actual irradiation process. If the frequency of obtaining the additional images is high, and a rapid automatic collation of the images is performed, an almost continuous guiding of the treatment is possible. This facilitates for example guidance of the irradiation according to a movement of the cancerous tumor, due to internal organ movements resulting from respiratory movement of the lung.

[0235] The following description describes in more details a possible method for guiding an external beam radio therapy equipment according to the present invention.

[0236] The position of the three-dimensional element 7 may be determined by producing a series of images 4. The images 4 are entered into the computer. The computer calculates and saves the mutual relationship between the three-dimensional element 7 and the tumor. The mutual relationship has been derived by establishing a distance between the tumor 6 and the three-dimensional element 7, which distance is fixed during any kinds of movements of tissue inside the body in relation to for example the bone structure or movements of the body 1 as a whole. By the wording a fixed distance is meant that the tumor 6 and the three-dimensional element 7 have substantially no relative movement in relation to one another.

[0237] Establishing a preliminary position of the three-dimensional element 7 in the image 4 in relation to a reference may, according to the invention, be performed by identifying a known geometrical shape, such as the pitch distance between the windings of a coil shaped element 7, the bending in a structural transition of the three-dimensional element 7, a circumference or contour of the three-dimensional element 7, etc.

[0238] Subsequently, a preliminary position of the irradiation equipment 2 is automatically established by a computer. Establishing a preliminary position of the irradiation equipment 2 in relation to the reference may be performed by measuring the distance from the position, where radiation is emitted from the irradiation equipment and to starting point/set-up point in the image 4, including identifying a level in which the plane of the image 4 is positioned. Establishing of a preliminary position of the irradiation equipment in relation to the reference may also be performed by identifying where a certain bone structure in the body is positioned in relation to the irradiation head or it may be performed by establishing the mutual relationship between the couch and the position where the radiation is emitted from the irradiation equipment.

[0239] During the period of time in which the irradiation equipment 2 is activated in order to irradiate the tumor 6, any possible displacement of the element 7 is monitored. Provided a possible movement is being detected the irradiation equipment 2 is adjusted in response to the movement of the element so that the irradiation of the tumor 6 is executed as precisely as possible.

[0240] In this regard, the irradiation equipment 2 comprises, among other features, the couch where the patient may lie or sit, the irradiation source, the irradiation beam, and plates or shield defining the shape of the beam.

[0241] Adjusting the irradiation equipment 2 may therefore be an adjustment of the position of the irradiation equipment 2, an adjustment of the position of the couch 5 in relation to the equipment 2, an adjustment of the power of the irradiation source, an adjustment of the focal point of the beam 3, an

adjustment of the intensity of the beam 3, an adjustment of movement of the plates or the shield in order of changing the shape of the beam 3 and so forth. The adjusting of the irradiation equipment 2 may furthermore be a deflection of the irradiation beam 3 in relation to a body to be irradiated.

[0242] The adjustment of the irradiation equipment 2 may also be to turn down the power of the irradiation source, when the element 7 is monitored to be outside a certain area, and to turn on the power again, when the element 7 is within the certain area again. It may furthermore be possible to adjust the irradiation power during the irradiation period, in order to subject some areas of the tumor 6, to higher dose of irradiation than other areas, e.g. subjecting the irradiation margin area to smaller dose of irradiation than the tumor 6 itself, or subjecting some very critical areas in the human or animal body to smaller dose of irradiation than the tumor 6 itself.

[0243] Instead of turning on or turning down the power, the irradiation beam may be deflected or the focal point of the irradiation beam may be changed. By irradiating the whole area of the tumor 6 it may be necessary to irradiate the tumor 6 by moving the irradiation beam in a predefined movement pattern.

[0244] Monitoring a possible movement of the three-dimensional element 7 in relation to the irradiation equipment 2 may be performed in pre-selected intervals such as 10-20 times a second, such as 1-2 per minute, etc. depending on the medical imaging equipment and based on the expected frequency of movement of the three-dimensional element 7.

[0245] When planning irradiation of the patient, an irradiation margin is used in order to be certain that the tumor 6 is irradiated sufficiently, even though the step of monitoring and of adjusting provides for a decrease of the size of the irradiation margin.

[0246] Before performing the actual irradiation, the three-dimensional element 7 having been positioned in relation to the tumor 6 is located when the patient is lying on the irradiation couch or when the patient in any other way is located in the irradiation room. The location of the three-dimensional element 7 may in one embodiment be established by deriving a high-voltage image 4 using the irradiation equipment 2 itself. The patient or the irradiation equipment 2 is positioned so that the three-dimensional element 7 is positioned as previously planned, and so that the reference is centered in the middle of the three-dimensional element 7. Hereby a starting point is established also called the preliminary position of the irradiation equipment 2 and of the element 7 in relation to the reference.

[0247] The reference may in this aspect be any previous image 4 derived identifying the tumor 6 in relation to the three-dimensional element 7. The previous image 4 may also be the last image 4 derived in order to monitor a possible movement of the three-dimensional element 7, or the reference may be an image 4 derived during the pre-examination. By the previous image 4 is meant an image 4 derived before the present image 4, in which previous image 4 the position of the three-dimensional element 7 has been established.

[0248] In another aspect, the reference may be the couch on which the patient is located during the irradiation or the reference may be the irradiation equipment 2 itself. The reference may also be a certain bone structure or another identifiable structure inside or outside the human or animal body.

[0249] By automatically monitoring and detecting a possible movement of the three-dimensional element 7, the method is capable of adjusting the irradiation equipment 2 or

the patient in relation to each other every time the three-dimensional element 7 is moving from the established preliminary position. It is hereby obtained to compensate for frequent movement of the tumor caused for example by respiration or small movements made by the patient, said movements being made by force, being made voluntary by the patient or being made involuntary by the patient. A considerable improvement of the accuracy of the irradiation is accomplished and the irradiation of healthy tissue is reduced.

[0250] FIG. 14 shows that merging different images 4 together based on a center of the images being positioned within boundaries of the three-dimensional element 7 gives a very accurate localization of the tissue of interest, for example the prostate.

[0251] By sampling images 4 during the irradiation of the tumor the monitoring of any possible movement of the three-dimensional element 7 and thus of the tumor 6 may be equalized momentarily all most the instance the movement appears. The sampling frequency may vary from ten images per second or faster to one image per three second depending on the equipment used for producing the images 4.

[0252] High voltage equipment such as the irradiation equipment 2 itself has a sampling frequency (or sampling rate) less than for example MR-scanning equipment. However, when using the irradiation equipment 2 itself the other equipment is dispensable.

[0253] Often, X-ray is used to establish the first image 4 for localization of the tumor 6 in relation to the three-dimensional element 7, but other equipment such as CT-scanning equipment and MR-scanning equipment may be used likewise. The position of the tumor 6 in relation to the three-dimensional element 7 is thus determined prior to the patient entering the irradiation room.

[0254] In one aspect of the present invention the patient itself inputs the first image 4 into the computer of the irradiation equipment, said first image 4 being relied upon as the previous image 4 and thereby as the reference in the computer of the irradiation equipment 2. Subsequently, the computer controls the irradiation equipment 2 for producing an image 4 for establishing the position of the element 7 in relation to the irradiation equipment 2. Then the computer adjusts the irradiation equipment 2 if necessary in relation to the position of the element 7 and the irradiation of the human or animal body begins.

[0255] The three-dimensional element 7 may be all kinds of objects provided in the body for a number of other reasons. Such objects may be all kinds of endoluminal prosthesis often being tubular, such as a element 7 placed in the urethra and other natural cavities, such as the urological tract, the urethra, the biliary tract, the airways, the intestine, or the blood vessels in the human body.

[0256] If an element 7 is already present in the vicinity of the tumor to be irradiated, the element 7 will secure the passage of the liquid, gas or solid inside that natural cavity, as mentioned above. It is well known that the tissue having been irradiated becomes distended and thereby may cause a reduction of the volume of the natural cavities. A three-dimensional element 7, such as a tubular endoluminal prosthesis can help to counteract this reduction of the volume of the cavity.

[0257] For the reason of avoiding a reduction of the volume of the natural cavities one or more elements 7 may be provided which may be used in guiding the irradiation equipment 2 in order to adjust for the aforementioned momentary movements during the irradiation.

[0258] Furthermore the three-dimensional element 7 may in another aspect of the present invention have a shape enabling insertion and retraction in a natural cavity. Additionally, when inserted into the cavity a part of the element 7 may expand in order to provide a force against the surrounding wall of the cavity so as to fasten the element 7 in this position. In other embodiments of the present invention the fastening of the element 7 in relation to the surrounding walls of the cavities may be done by at least a part of the element 7 being attached at least partly to tissue outside the natural cavity or by the element 7 having an Y-shape, an I-shape or the like shapes processing a locking mechanism blocking movements in the longitudinal direction of the cavity, such as the ureter, vein or the like cavity.

[0259] An example of such a three-dimensional element 7 according to the present invention is a tubular stent used for insertion into the urethra in the vicinity of the prostate as shown in FIGS. 4, 5, 7 and 8. When the stent has been positioned in the part of the male urethra passing through the prostate and expansion of the end of the element 7 closest to the external urethral sphincter has occurred, the element 7 will remain in position and allow urinary passage without obstructing the function of the sphincter.

[0260] The wire design of the element 7 is of particular advantage when the element 7 is to be removed or retracted from a body cavity because the element 7 of a shape memory alloy becomes soft when it is cooled. The element 7 may be removed by grasping in any part of the helically wound wire and subsequently pulling the coil out of the cavity as a wire. Furthermore, the element 7 may have a different design than a coiled wire and the element may be made of other alloys so when cooled the element 7 becomes super elastic and is retractable by folding up the element 7 before retraction.

[0261] A further advantage of using a three-dimensional element 7 with a kind of locking mechanism is that the element 7 will move together with the tumor 6 during respiration or other partly movements of the human or animal body or during total movement of the same body as shown in FIG. 7. Due to the fact that the element 7 moves with substantially no relative movement in relation to the tumor 6, the irradiation equipment 2 may be adjusted in relation to the possible movement of the three-dimensional element 7 in order to accurately irradiate the tumor 6. In an image 4 produced by the irradiation equipment 2 the computer is not able to detect the tumor 6 since it is not visible in such image 4. However, a three-dimensional element 7 made of metal, such as stainless steel, titanium, platinum, palladium, gold, nickel-titanium and other alloys thereof is easier to detect in such an image 4. Therefore, a possible momentary movement of the element 7 is also detectable and the irradiation equipment 2 may be adjusted to equalize such a momentary movement.

[0262] The element 7 may also be of other biologically compatible materials, such as polymers and biological material being detectable in some images.

[0263] The three-dimensional element 7 may have all kinds of shapes detectable in image 4 derived and produced by all kinds of medical imaging equipment, said shape resulting in a predefined geometrically structure in said image 4. In order to monitor a possible movement, the predefined geometrically structure is identified in the image 4 and the adjusting of the irradiation equipment 2 may either move the body or properly adjust the position of other parameters of the irradiation equipment 2 in response to this movement.

[0264] When using the aforementioned element 7 inserted in the urethra in the vicinity of the prostate the predefined geometrically structure may be the diameter of the helically wound coil or the pitch distance between the windings of the coil. This geometrically structure gives a number of detectable points and is automatically detectable in the image 4 by image processing being implemented on a computer.

[0265] Another predefined geometrically structure of the element 7 may be the angle  $v$  between the straight part of the element 7 shown in FIG. 7 and the conical part or the predefined geometrically structure may be transition point in which the straight part of the element 7 and the conically part of the coil intersect. This detection, like the aforementioned ways of detection, also provides a three-dimensional positioning of the element 7.

[0266] Elements 7 and other kinds of endoluminal prosthesis are often manufactured in various lengths and the aforementioned predefined geometrically structure is independent of this variation in the length of stents and other endoluminal prosthesis.

[0267] The three-dimensional element 7 may, as mentioned above, possess all kinds of shapes giving a recognizable defined geometrically structure in the aforementioned image 4. Examples of such other shapes are shown in FIG. 8-11. Instead of a helically wound kind of coil as shown in these figures the three-dimensional element 7 may be a tube having a solid wall and/or an expandable part or different kinds of locking mechanisms. The wall of the tubular element 7 can be made from wire being wound in different patterns, such as cross-patterns, knitting-patterns or the like. The three-dimensional element 7 may, in another aspect of the present invention, be an implant or the reference may be such implant.

[0268] By the term mega-voltage equipment is meant all sorts of electron accelerators operating over 150 kV, preferably above 1 MV, and preferably below 50 MV. Such an electron accelerator may be the irradiation equipment 2 used for treating the patient by irradiating the tumor 6.

[0269] By medical imaging equipment is meant all kinds of equipment usable for producing the image 4 of disordered tissue and the three-dimensional element 7. Such equipment may be Magnetic Resonance scan (MR-scan), Nuclear Magnetic Resonance scan (NMR-scan), Magnetic Resonance Image scan (MRI-scan), Computerized Tomography scan (CT-scan), Cone Beam CT-scan, Positron Emission Tomography (PET), Single Positron Emission Computed Tomography (SPECT), Single Positron Emission Tomography (SPET), Image-Guided-Radiation-Therapy (IGRT), Ultrasound-scan, or X-ray, high-energy photons equipment or high voltage equipment.

[0270] The term shape memory alloy is defined as a metal having transformation from martensite to austenite at a certain temperature range (Austenite Start to Austenite Finish (AS to AF)). Within this temperature range (AS to AF) the expansion of the three-dimensional element 7 starts and the expansion stops when all the martensite is transformed into austenite. The element 7 "remembers" at this temperature range (AS to AF) its original shape. At another temperature range (Martensite Start to Martensite Finish (MS to MF)) the alloy reverses to martensite. Below this other temperature (MF) the element 7 is easily deformable by hand and the element 7 may therefore be easily deformable inside the body cavity and retracted through the natural opening in which the element 7 was inserted. Alternatively the element may be retracted through another natural opening than the one

through which it was inserted. The shape memory alloy may also be called temperature-activated alloy.

[0271] The term shape memory alloy may also be a metal having super elastic properties at a certain temperature, such as about 37° C., being the body temperature, and a plasticity at a another temperature, such as below 0° C. By the wording super elastic properties is meant an alloy which can be elastically deformed up to very high deformation rates compared to other metals and which alloy does not necessarily have a temperature (AS) at which the material is capable of remembering an original shape.

[0272] The shape memory alloy may be a nickel-titanium alloy, a nickel-titanium-cobalt alloy, other transition and precious metal alloys or thermoplastic heat settable material exhibiting shape memory characteristics. Heating of the wire may be accomplished by induction heating, immersion heating, application of RF energy, or by flushing the area of the three-dimensional element 7 with a fluid at the specified temperature.

1-47. (canceled)

48. A method for identification of an element in two or more images, the method comprising the steps of,

identifying, in an image, a single integral three-dimensional element visible in the image, said single integral three-dimensional element being in position in a human body or an animal body in relation to a bodily matter of interest within the human body or the animal body, the method comprising the steps of:

identifying in a first image the single integral three-dimensional element, visible in the first image,

identifying in a second image the same single integral three-dimensional element, visible in the second image, collating the first image and the second image based on a determination of the position of the one and same single integral three-dimensional element in the first image and the position of the one and same single integral three-dimensional element in the second image.

49. A method according to claim 48, said method comprising the further step of,

establishing a position and/or establishing an extension and/or establishing a shape of the at least one single integral three-dimensional element in reference to the bodily matter of interest within the human body or the animal body, the establishing being based on collating the first image and the second image.

50. A method according to claim 48, where identifying the position of the at least one single integral three-dimensional element is used also for determining at least one of the following physical characteristics in relation to the at least one single integral three-dimensional element: A shape of the element and/or an extension of the element.

51. A method according to claim 48, wherein the two or more images, being derived by different types of imaging equipments, are collated based on determination of at least one of the following characteristics of the single integral three-dimensional element, in each of the images: the position or the extension or the shape of the element.

52. A method according to claim 48, wherein the two or more images, being derived under different set-up conditions when deriving the images, are collated based on determination of at least one of the following characteristics of the single integral three-dimensional element, in each of the images: the position or the extension or the shape of the element.

53. A method according to claim 52, wherein the two or more images are derived with a time interval between the deriving of the images and are collated based on determination of at least one of the following characteristics of the single integral three-dimensional element, in each of the images: the position or the extension or the shape of the element.

54. A method according to claim 48, wherein the two or more images are being collated automatically, based on an automatic identification of the single integral three-dimensional element in the different images.

55. A method according to claim 53, wherein more images are derived with a time interval between the deriving of the images and are being collated automatically and continuously, based on an automatic identification of at least one of the following characteristics of the single integral three-dimensional element, in each of the images: the position or the extension or the shape of the element.

56. A method according to claim 48, said method comprising the further step of,

setting up treatment specifications according to the information in the two or more collated images.

57. A method according to claim 48, said method comprising the further step of,

comparing at least one of the following characteristics of the bodily matter of interest: the position or the extension or the shape of the matter,

in reference to at least one of the following characteristics of the single integral three-dimensional element, in each image: the position or the extension or the shape of the element.

58. A method according to claim 48, said method comprising the further step of,

using at least one of the following characteristics of the single integral three-dimensional element: the position or the extension or the shape of the element, relative to a reference in the first image as a reference-position,

comparing at least one of the characteristics of the single integral three-dimensional element: the position or the extension or the shape of the element, relative to the same reference in the second image, with the reference-position in the first image

59. A method according to claim 58, said method comprising the further step of,

guiding a treatment equipment according to the comparison of at least one of the characteristics of the single integral three-dimensional element relative to the reference in the second image with at least one of the characteristics of the single integral three-dimensional element relative to the reference-position of the same reference in the first image.

60. A method according to claim 59, wherein the treatment equipment to be guided is an external beam radio therapy equipment.

61. A method according to claim 57, wherein the same single integral three-dimensional element is used for setting up treatment specifications, based on collated pre-treatment images, and for comparing at least one of the characteristics of the single integral three-dimensional element, relative to a reference in one or more just-before-treatment-images or in one or more during-treatment-images, with the reference-position in the pre-treatment images, and possibly the step of guiding a treatment equipment, where the same single inte-

gral three-dimensional element possibly is used without reinsertion or re-positioning of the single integral three-dimensional element.

62. A method according to claim 48, wherein the imaging equipment is medical imaging equipment such as Magnetic Resonance scan (MR-scan), Nuclear Magnetic Resonance scan (NMR-scan), Magnetic Resonance Image scan (MRI-scan), Computerized Tomography scan (CT-scan), Cone Beam CT-scan, Positron Emission Tomography (PET), Single Positron Emission Computed Tomography (SPECT), Single Positron Emission Tomography (SPET), Image-Guided-Radiation-Therapy (IGRT), Ultrasound-scan, or X-ray, high-energy photons equipment or high/mega voltage equipment.

63. A method according to claim 48, wherein the single integral three-dimensional element (7) is intended for being placed and fixed inside a natural body cavity of the human body or the animal body.

64. A method according to claim 63, wherein the at least one single integral three-dimensional element is a tubular endoluminal prosthesis.

65. A method according to claims 63, wherein the at least one single integral three-dimensional element (7) is a helical coil of at least one wire.

66. A method according to claim 48, wherein at least a part of the at least one single integral three-dimensional element (7) has a shape allowing passage of a liquid, gas or solid inside the cavity in which the element is in position.

67. A method according to claim 66, wherein the at least one single integral three-dimensional element is a tubular endoluminal prosthesis.

68. A method according to claims 66, wherein the at least one single integral three-dimensional element (7) is a helical coil of at least one wire.

69. A method according to claim 48, wherein said cavity has at least one surrounding wall, and wherein the at least one single integral three-dimensional element (7) has a collapsible design enabling a collapsed design before the element (7)

is positioned in the cavity, and enabling an expanded design when the element (7) is in position in the cavity.

70. A method according to claim 48, wherein the at least one single integral three-dimensional element (7) is in position in the body preliminary to deriving the first image and the second image, said positioning of the element having been performed through a natural opening of the body (1) without substantially penetrating any tissue of the body (1).

71. A system for carrying out the method according to claim 48, comprising image deriving equipment for identifying a single integral three-dimensional element (7) in the first image and in the second image, image processing equipment for identifying the position of the single integral three-dimensional element (7) in the first image and in the second image, image processing equipment for collating the first image and the second image, said collating being based on a determination of at least the position of the one and same single integral three-dimensional element in the first image and of at least the position of the one and same single integral three-dimensional element in the second image.

72. A system according to claim 71, wherein the imaging equipment is medical imaging equipment such as Magnetic Resonance scan (MR-scan), Nuclear Magnetic Resonance scan (NMR-scan), Magnetic Resonance Image scan (MRI-scan), Computerized Tomography scan (CT-scan), Cone Beam CT-scan, Positron Emission Tomography (PET), Single Positron Emission Computed Tomography (SPECT), Single Positron Emission Tomography (SPET), Image-Guided-Radiation-Therapy (IGRT), Ultrasound-scan, or X-ray, high-energy photons equipment or high/mega voltage equipment.

73. A system according to claim 71, wherein the at least one single integral three-dimensional element (7) has a design enabling at least one of the following operations: insertion and retraction of the element (7) with specifically adapted endoscopic equipment.

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