

TITLE

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MEDICAL IMPLANT WITH AN IMPLANT SCREW

TECHNICAL FIELD

10 The present invention relates to a medical implant with an implant screw, preferably a pedicle screw, as well as a method for planning the radiation in the medical radiation therapy.

PRIOR ART

15 Medical implants, and spinal implants in particular, often feature implant screws (bone screws) to connect the implant to one or more of a patient's bones, for example by screwing the implant screws through an opening in another part of the implant into the bone. The implant screws therein can be connected to each other by other implant parts, as is the case, for example, in spinal implant systems with pedicle screws and connecting
20 rods.

Implants, and in particular implant screws and bone screws, are normally made of metal, for example titanium and/or a titanium alloy. Such implants are radio-opaque and allow the exact position of the implant (for example, the pedicle screw) to be determined during an
25 examination of the patient using an imaging technique such as computed tomography (CT). Despite this advantage, such metal implants obstruct the view of the bone connected to the implant and the surrounding tissue during the radiographing process, as they are radio-opaque and also cause scattering effects during the radiographing process, which additionally produce artifacts in the area of the implant. Due to their radio-opacity, metallic
30 implants also interfere with radiation therapy for cancer patients, as the relatively large metallic mass causes scattering phenomena that reduce the effectiveness of the radiation, thus requiring a higher radiation dose, which in turn can cause side effects in the surrounding tissue.

In order to overcome the aforementioned disadvantages of metallic bone implants, bone implants or bone implant systems, respectively, made of non-metallic composite materials have been developed, which are generally radiotransparent and do not exhibit the
5 aforementioned disadvantages. Implants or implant systems, respectively, made of non-metallic composite materials based on carbon fiber-reinforced polyether ether ketone (PEEK) are preferred on the market. The implants in question may be, for example, cages, bone plates, pedicle rods, tulips, or pedicle screws.

10 Due to their radio transparency, these non-metallic implants require markers for detection in imaging procedures such as X-ray, CT, and magnetic resonance imaging (MRI), marking (markers). These markers are usually made on the basis of metals, particularly on the basis of tantalum or titanium and their alloys, and are inserted into or attached to the implant, respectively. Known designs of such markers are spherical or wire-shaped or in
15 the form of a coating.

Document US 10,154,867 B2 describes various embodiments of a bone screw made of composite material. In particular, this may be a pedicle screw that is partially coated with a metallic outer layer.

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Document US 10,617,458 B2 describes, as in US 10,154,867 B2, various embodiments of a bone screw made of composite material. Embodiments are disclosed in which the screw tip or the end of the screw thread in the direction of the longitudinal axis is coated with a radiopaque material.

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Document US 2015/0297267 A1 discloses a pedicle screw made of a composite material, the thread and screw tip of which are coated with a titanium layer.

The above-mentioned state-of-the-art implants have the disadvantage that, on the one hand,
30 the radiotransparency of the components is severely restricted due to the radiopaque coatings used and, on the other hand, the determination of the spatial position and orientation of the implants is inaccurate.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a medical implant that is as radiotransparent as possible, enabling particularly accurate determination of the spatial
5 position and orientation of the implant in an imaging procedure.

To solve this problem, a medical implant is proposed as specified in claim 1. Claim 16 specifies a method for planning the radiation in the medical radiation therapy, which is preferably based on such a medical implant. Advantageous embodiments of the invention
10 are specified in the dependent claims.

The present invention therefore provides a medical implant with an implant screw, in particular a pedicle screw, which comprises a screw head and a threaded shaft and is made of a plastic material, wherein the implant comprises radiopaque markers to allow
15 determination of the spatial position and preferably the orientation of the implant screw in an imaging procedure.

Therein, one or more of the markers together form a ring with a ring center located inside the screw head. Another of the markers is located on or in the threaded shaft.

20 By placing one of the markers on or in the threaded shaft of the implant screw and forming a ring with one or more of the markers, the center of which is located within the screw head, it is possible to determine not only the position of the implant very accurately in an imaging process, such as in particular by means of computed tomography (CT), but also its orientation. For this purpose, the position of the screw head can be determined by means of
25 the marker or markers forming the ring, and the direction along which the threaded shaft extends from the screw head can be determined by means of the additional marker. Since the geometry of the implant screw and, in particular, the length of the threaded shaft are usually known, the position and orientation of the implant screw can be determined very accurately. If the marker or markers forming a ring are not part of the implant screw but, as
30 is preferred (but not mandatory), another part of the implant has this marker or these markers forming a ring, the orientation, i.e., in particular the inclination, of the implant screw relative to this other part of the implant can also be determined. Since the imaging method reveals a marker ring in the area of the screw head instead of, for example, only a

marker point, it is possible to determine not only the position of the screw head with particular accuracy (due to the arrangement of the ring center within the screw head), but also its orientation or the orientation of another part of the implant relative to the screw. The combination of ring and, for example, point visible in the imaging process is not only
5 immediately identifiable as a screw by the observer, but also allows him to intuitively recognize the orientation of the screw in the body in the images, which are usually illustrated in a two-dimensional manner. The arrangement of the ring center within the screw head has therefore proven to be particularly advantageous.

- 10 The markers can be designed in particular so that they are relatively clearly visible in imaging procedures, i.e., they provide a strong contrast, in particular by being highly radiopaque, which allows the spatial position and orientation of the implant to be determined with particular accuracy. Since the radiopacity only affects the geometrically limited markers and is therefore concentrated in a few places on the implant, the implant
15 can otherwise be designed to be largely radiotransparent.

The precise determination of the spatial position and orientation of the implant, and in particular of the implant screw, by means of an imaging method, i.e. without contact, enables, for example, the implant to be checked or even monitored after it has been
20 implanted in a human or animal body. In a pedicle system, for example, the tilt/inclination of the pedicle screw relative to a fastening element often referred to in technical jargon as a tulip, which serves to connect the pedicle screw to a connecting rod, can be determined. Using time-delayed CT images, the stability of the vertebral fixation using the implant can be verified or any loosening of the fixation of the tulip to the connecting rod can be
25 detected.

Imaging methods are procedures, particularly in medicine, which enable the implant implanted in the body of a human or animal patient and/or the surrounding body tissue to be visualized without contact. In particular, imaging methods refer to various apparatus-
30 based examination methods which provide two-, three- or higher-dimensional image data of organs and structures of the patient and/or the implant implanted therein and are often used primarily for the diagnosis of disease-related changes. Examples of imaging methods include X-rays, computed tomography (CT), ultrasound, and magnetic resonance imaging

(MRI).

A medical implant is an artificial device which is implanted or can be implanted into the human or animal body and is usually intended to remain there permanently or at least for a
 5 prolonged period of time, i.e., at least several hours or days. For this purpose, the implant is usually anchored in a part of the body, usually a bone or cartilage, by means of an implant screw. The implant screw usually has an external thread that allows it to be screwed into the corresponding body part.

10 The threaded shaft of the implant screw usually extends from the screw head to a free end of the threaded shaft, i.e., the screw tip. The external thread preferably, but not necessarily, extends continuously over the entire length of the threaded shaft. In certain embodiments, the threaded shaft may also have one or more threadless sections, i.e., the external thread may be interrupted once or several times in the longitudinal direction. A threadless section
 15 may be present in particular in the area adjacent to the screw head. However, the external thread preferably extends to the tip of the screw.

The threaded shank and, in particular, the external thread define a main longitudinal center axis of the implant screw, which extends centrally and longitudinally through the threaded
 20 shank.

The screw head of the implant screw is preferably round, or even better, essentially spherical. "Essentially spherical" means that it can comprise flat spots, especially because of an engagement structure, whereas a spherical overall shape is preferred. The screw head
 25 is suitable for being attached to another component as a result of the implant screw being rotatable in a polyaxial manner relative to this component. The engagement structure advantageously serves for screwing in the implant screw using a suitable tool. The other component mentioned may be a further part of the implant. Depending on the case, the ability to pivot may be provided before the implant screw is definitively fastened to the
 30 other part, for example by tightening a clamping part, or it may be provided afterwards. The polyaxial pivotability may be provided in particular by a type of ball joint.

The implant screw may in particular be a pedicle screw, i.e. a screw designed to be

screwed into a vertebral body of a human or animal spine. The screw head is then preferably designed for connection to a connecting rod by means of, for example, a tulip-shaped fastening element. The implant screw and the connecting rod then form components of a pedicle system. However, it is also possible that the implant screw serves,
5 for example, to attach an implant plate to a bone. The implant may therefore also have several implant screws, in which case some or all of the implant screws may comprise the aforementioned radiopaque markers.

The aforementioned determination of the spatial position of the implant screw means that
10 an imaging technique can be used to determine the location of the implant screw in the patient's body. The location is advantageously determined in relation to a reference point that may be located inside or outside the body. However, when determining the spatial position, it is generally not necessary to determine the spatial orientation of the implant screw. This means that it is possible, for example, to determine only where the screw is
15 located as a whole, for example in relation to its center of mass, but not, for example, in which position the screw is located and in which direction the threaded shaft extends. However, it is possible to determine the spatial orientation of the implant screw in the implant specified here due to the combination of one or more of the markers forming a ring and another of the markers being arranged on or in the threaded shaft.

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Radiopacity, also known as X-ray opacity, refers to the property of materials or components to allow X-rays to pass through them. A radiopaque material or component is less permeable to X-rays than other surrounding materials or components and therefore attenuates the X-rays when they pass through it. In the present case, the markers mentioned
25 therefore relate to a material or component (or part of a component) that is less permeable to X-rays than other parts of the implant. In particular, the markers are less permeable than the plastic material of the pedicle screw. In imaging procedures, the markers therefore appear lighter or darker than the surrounding areas, depending on the type of imaging.

30 The radiopacity of the markers preferably differs by at least an integer multiple, preferably at least twice, even more preferably at least five times, and most preferably at least ten times, from that of the plastic material of the pedicle screw.

A ring is generally regarded as a geometric structure that revolves around a center point and can extend in both a radial and axial direction. Due to its radial extension, the ring can, for example, be formed by a surface extending between two concentric circles. Due to its axial extension, the ring can also be formed by a hollow cylindrical structure, for example.

- 5 Usually, the ring formed by the marker(s) has both a certain radial and a certain axial extension. This means that the ring can, for example, be formed by a hollow cylindrical structure which (due to its radial extension) can have a certain wall thickness. Thus, in the context of the present document, a hollow cylindrical structure as a whole is also considered to be a ring, with the center of the ring then located in the axial center of the
- 10 hollow cylindrical structure. The ring is preferably, but not necessarily, exactly circular.

In particular, if the ring is formed by several markers together, it can be formed by a common envelope of the corresponding marker or markers, respectively. The markers can, for example, each be point-shaped or spherical and form the corners of any regular

15 polygon. The number of corners of the polygon can be three, four, five, or greater than five.

However, the ring is preferably formed by a single marker that is continuous in the circumferential direction. Such a ring marker not only makes the implant particularly easy

20 to manufacture, but also allows the position and orientation of the implant screw to be easily recognized in imaging procedures.

With the help of the ring formed by the marker or markers, respectively, with the ring center within the screw head and the additional markers located on or in the threaded shaft,

25 the position and orientation of the implant screw can not only be detected in the imaging process, but also measured clearly and precisely. This enables, in particular, a contactless monitoring of the implant screw after implantation. In a pedicle system, for example, a change in the angle of the screw relative to a connecting rod detected during monitoring using time-delayed CT images may indicate that the fixation of the tulip on the rod has

30 become loose. Conversely, monitoring can be used to verify the stability of the fixation.

In a particularly preferred embodiment, the center of the ring is located exactly in the center of the screw head. This makes the position of the screw head particularly intuitively

to recognize in imaging procedures. If the marker or markers forming the ring are not located in or on the implant screw itself but, as is preferred, on another part of the implant, the arrangement of the ring center in the center of the screw head also has the advantage that the position of the screw head is always correctly indicated regardless of the pivoting
5 of the screw relative to this other part. It is particularly preferred if the ring center is also located in a center of rotation, pivot point, or in a pivot axis of the implant screw. If the implant has a fastening element for attaching, in particular fixing, the implant screw, preferably to a connecting rod, the ring center is preferably located in a center of rotation, pivot point, or in a pivot axis of the implant screw when the fastening element is fixed to
10 the implant screw. It is also preferred that the ring formed by the one or more marker(s) comprises an inner diameter that is greater than an outer diameter of the screw head.

The marker arranged on or in the threaded shaft is preferably arranged along a longitudinal direction extending from the screw head to a free end of the threaded shaft, in the last third
15 of the threaded shaft. Compared to an arrangement of the marker close to the screw head, this makes it easier to determine the orientation of the screw. It is particularly preferred that the marker arranged on or in the threaded shaft is even located at the free end of the threaded shaft, i.e., at the tip of the screw. This not only makes it particularly easy to determine the orientation of the screw, but also allows the observer to immediately and
20 intuitively recognize the length of the implant screw in the imaging process.

In order to enable a particularly simple manufacture and to make the implant screw particularly stable and good at conducting force, it is preferably designed entirely as a single piece.
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According to a particularly preferred embodiment, the implant has a fastening element for attaching, in particular fixing, the implant screw. The fastening element, which particularly may be tulip-shaped, is preferably used to fasten the implant screw to a connecting rod. The implant screw is then preferably a pedicle screw. In such a design, the fastening
30 element preferably comprises the one or more markers forming a ring. The arrangement of the marker(s) on the fastening element allows not only the position and orientation of the implant screw to be determined, but also its inclination relative to the fastening element. In other embodiments, it is of course also possible for the screw head to have the marker or

markers forming a ring.

The marker or markers forming a ring are preferably formed by a screw element that can be screwed onto the fastening element. The fastening element and/or the screw element are preferably each entirely formed as a single piece. The screw element, which can be screwed onto the fastening element or screwed into it, is preferably made entirely from a radiopaque material. Alternatively, the screw element can also comprise a radiopaque coating.

10 In a particularly preferred embodiment, the screw element serves to hold the implant screw on the fastening element.

The implant screw attached to the fastening element is advantageously pivotable with the threaded shaft relative to the fastening element in a polyaxial manner around the ring center. Due to the ring marking, the inclination of the implant screw relative to the fastening element can be determined in the imaging process.

One or more markers may be arranged on or in the threaded shaft. The marker or markers, respectively, arranged on or in the threaded shaft can also be of any shape. According to a preferred embodiment, however, at least one of the markers arranged on or in the threaded shaft comprises a spherical form. This makes the marker particularly easy and clear to be recognized during the imaging process. For manufacturing reasons, it is also easier if exactly one marker is arranged on the threaded shaft.

25 In another, likewise preferred embodiment, the marker arranged on or in the threaded shaft is ring-shaped, in particular sleeve-shaped. Such a shape of the marker is particularly suitable for a cannulated implant screw. A channel extending in the longitudinal direction through the threaded shaft then preferably extends through the ring-shaped or sleeve-shaped marker, respectively, so that, for example, medication or bone cement can be delivered to the patient through the marker along the main longitudinal center axis of the implanted screw.

The ring center of the ring formed by the marker or markers is preferably located on the

main longitudinal center axis of the implant screw. Preferably, the marker located on or in the threaded shaft also forms a center point that is located on the main longitudinal center axis of the implant screw. In this way, the position of the implant screw can be directly determined based on the position of the markers visible in the imaging.

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The markers are advantageously each made of a metal, in particular tantalum or titanium. Metal is generally well suited as a radio-opaque material. Tantalum and titanium are particularly biocompatible and suitable for use in manufacturing.

- 10 The plastic material of the implant screw is preferably a thermoplastic material. Particularly preferred are so-called high-temperature thermoplastics from the families of polyaryletherketones, polyimides, and polysulfones. Polyetheretherketone (PEEK) has proven to be a particularly suitable plastic material. The plastic material PEEK has proven to be particularly suitable for pedicle screws in spinal implants, but also for other implants,
15 especially due to its hardness and durability as well as its good processability and biocompatibility.

- The plastic material of the implant screw is preferably fiber-reinforced, in particular carbon fiber-reinforced. In this way, a particularly high strength of the implant screw can be
20 achieved. The plastic material of the implant screw can thus be in particular a composite material, preferably in the form of carbon fiber-reinforced PEEK.

- The fiber length is preferably at least 1 mm. In order to achieve particularly good strength of the implant screw, the fibers advantageously have a length that corresponds at least to
25 the complete length of the implant screw along its main direction of extension. The fiber volume content is preferably in a range of 20 to 80%, more preferably in a range of 35 to 70%, and particularly preferably in a range of 45 to 60%.

- The implant screw can be manufactured in principle using a method commonly known in
30 the field of composites. These include, among others, pressing, winding, tape laying, and pultrusion methods. The pressing process described in document DE 44 45 305 C1 is preferred for manufacturing the implant screw and, if present, the fastening element, for example in the form of a tulip head. The implant can also be manufactured using so-called

additive manufacturing processes, such as 3D printing, or a combination of the above-mentioned processes. The preferred starting materials for these processes are so-called unidirectional preregs and tissue preregs. Both are geometrically flat or round starting materials. In the above-mentioned processes, the preregs are usually preformed into
5 preforms and welded under pressure and temperature, for example in a press tool, and then cooled.

The markers can be inserted or positioned mechanically, e.g. by pressing or screwing a marker into the tip of the implant screw or by inserting the marker into a tool mold in
10 which this marker is formed during the manufacture of the implant part, e.g. using the pressing method described in document DE 44 45 305 C1, and thus integrated into the implant part. In the case of the fastening element, this can be done, for example, by inserting a ring-shaped marker into a tool mold. Alternatively, a ring-shaped marker can be attached and positioned on the fastening element in such a way that the marker is screwed,
15 locked or latched into place on a main part of the fastening element. The marker or markers can be attached or integrated on the outside or inside of the fastening element.

Furthermore, the marker(s) can be applied to the implant screw or to another implant part, such as the fastening element, in particular, using known coating methods. Such coating
20 methods include, for example, electroplating methods, plasma coating, laser deposition welding, flame spraying, and 3D printing methods.

The above-mentioned methods for manufacturing a medical implant with integrated markers are preferably near-net-shape manufacturing methods, which means that implants
25 manufactured in this way generally require only minor post-processing in terms of shape and dimensions, during which the positioning of the markers is maintained.

The invention also relates to a method for planning the radiation in medical radiation therapy, in which one or more radiopaque markers are used in an imaging method as a
30 spatial reference for planning the therapeutic radiation of a human or animal patient, the one or more markers being attached on or inside the patient's body.

The one or more markers are each arranged on or in the threaded shaft of an implant screw, preferably a pedicle screw, which is made of a plastic material and anchored in the body,

preferably in a bone, of the patient. Said screw on or in the threaded shaft of which the one or more markers are arranged is, in particular, preferably an implant screw of a medical implant according to the above description.

- 5 The procedure for planning radiation in medical radiation therapy therefore includes the step of using one or more radiopaque markers in the imaging procedure as a spatial reference for planning the therapeutic radiation. The radiopaque markers arranged on the implant screws and used for radiation planning can also be referred to as passer markers or reference markers, or in English so-called fiducial markers.

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The one or more radiopaque markers arranged on the threaded shaft can be used in the aforementioned method, in particular to determine the spatial position of the body area or areas to be irradiated. Since the one or more screws made of a plastic material are usually firmly anchored in the body anyway, the radiopaque marker or markers arranged thereon
 15 can be used very easily for particularly precise and reliable planning of the therapeutic irradiation. For patients who require therapeutic radiation and who already have at least one such screw implanted in their body, this means that a further medical procedure to position reference markers can be partially or even completely eliminated. With the specified method, it is therefore possible to dispense with the implantation of markers
 20 specifically serving as a reference for radiation, since the markers of the implant screws already anchored in the patient can be used for the same purpose.

It is particularly advantageous if several such radiopaque markers, each anchored in the patient's body by a screw, are used to plan the therapeutic radiation. The radiopaque
 25 markers can then be used in particular to determine a spatial reference system for radiation planning.

The method is therefore particularly useful for spatially positioning patients during medical radiation therapy, wherein three or more radio-opaque markers are typically used in an
 30 imaging procedure to provide spatial reference points for a human or animal patient. For this purpose, preferably, at least three markers are attached onto or inside the patient's body to ensure accurate positioning. Positioning usually refers to the actual situation of the patient vs. the target situation, which can be seen from the radiation planning. It is

advantageous if the three markers can be clearly distinguished from each other in the imaging during radiation. For radiation planning, markers that are positioned close to, i.e., in the immediate vicinity of, the volume to be irradiated, which is e.g. formed by a tumor, are preferred. Implant screws with markers that are anchored in the spine are particularly

5 suitable for radiation planning in cases where the volume to be irradiated is located in the immediate vicinity of the spine or, for example, in the abdominal cavity and the spine is the nearest bone structure. Depending on the situation, radiation planning can also be based on the marker(s) of the implant screw(s) in combination with additional markers that have been implanted in the patient's body specifically for this purpose. The markers used for

10 radiation planning usually have a defined geometry (e.g., cylindrical, spherical, or ring-shaped) and are therefore preferably automatically recognizable by the positioning imaging and planning software. The specified method is preferably automated. The implant screws are preferably pedicle screws, which are advantageously made of a fiber-reinforced plastic material.

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BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the invention are described below with reference to the drawings, which are provided for illustrative purposes only and are not to be construed as

20 limiting. The drawings show:

- Fig. 1 a schematic view of a medical implant according to the invention in the form of a pedicle system with a plurality of pedicle screws, each of which is
- 25 implanted in a vertebral body and connected to each other by means of a connecting rod;
- Fig. 2 a perspective exploded view of a pedicle screw, as well as of a tulip head for attachment to a connecting rod, and of a washer of the implant of Fig. 1;
- Fig. 3 a top view of the screw head of a pedicle screw of the implant of Fig. 1 held
- 30 in the tulip head;
- Fig. 4 a side view of a possible first variant of a pedicle screw of the implant of Fig. 1 held in a tulip head, wherein the area of the screw tip is shown as a central cross-sectional view;

- Fig. 5 a side view of a possible second variant of a pedicle screw of the implant of Fig. 1 held in a tulip head, wherein the area of the screw tip is shown as a central cross-sectional view;
- Fig. 6a a side view of a pedicle screw held in a tulip head with the threaded shaft in a first pivot position;
- 5 Fig. 6b a side view of a pedicle screw held in a tulip head with the threaded shaft in a second pivot position;
- Fig. 7 a central cross-sectional view of a tulip head of an implant according to the invention with a ring marker screwed on according to a first embodiment;
- 10 Fig. 8 a central cross-sectional view of a tulip head of an implant according to the invention with a ring marker screwed on according to a second embodiment;
- Fig. 9a a schematic representation of a conical space spanned by the ring marker on the tulip head and a further marker on the screw tip of a pedicle screw of one of the implants of Figures 1 to 8;
- 15 Fig. 9b the same schematic representation as in Fig. 9a, but from a different viewing angle;
- Fig. 10a a schematic representation of the dimensions in the direction of the central axis of the tulip head of the pedicle screw of Fig. 9a (x-y plane);
- Fig. 10b a schematic representation of the dimensions in the direction perpendicular to the center axis of the tulip head of the pedicle screw in Fig. 9a (y-z plane);
- 20 Fig. 11 a schematic representation of the dimensions in any direction relative to the center axis of the tulip head of the pedicle screw in Fig. 9a; and
- Fig. 12 a schematic view of a medical implant with a plurality of pedicle screws, each implanted in a vertebral body and having a radiopaque marker, which are used in a medical radiation therapy method according to the invention as a spatial reference for planning the therapeutic irradiation.
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DESCRIPTION OF PREFERRED EMBODIMENTS

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Figures 1 to 8 show various embodiments of medical implants according to the invention and parts thereof. Figures 9a to 11 show geometric representations of the markers of these implants and the dimensions resulting from imaging. Elements of different embodiments

that are identical or have a similar function are designated with the same reference numerals.

Figure 1 shows a preferred embodiment of a medical implant according to the invention in the form of a pedicle system 1. The pedicle system comprises a plurality of implant screws 4, which can also be referred to as pedicle screws, each of which is screwed into a vertebral body W of a patient's spine. Each of the implant screws 4 is attached to a connecting rod 3 by means of a tulip head 5. The connecting rod 3 thus connects the implant screws 4 to each other and thereby blocks the vertebral bodies W. The pedicle system 1 can, for example, serve to relieve the intervertebral discs B arranged between the vertebral bodies W.

In principle, the pedicle system 1 as a whole forms a medical implant 2. However, a medical implant 2 is also formed by each of the implant screws 4 themselves and by each common pair of an implant screw 4 and a tulip head 5.

A medical implant 2 according to the invention, comprising an implant screw 4, a tulip head 5, and a washer 6, is shown in Figure 2. The implant screw 4 of this implant 1 comprises a spherical screw head 41, from which a threaded shaft 43 extends to a screw tip S. The threaded shaft 43 is provided with an external thread, which allows the implant screw 4 to be screwed into and anchored in a bone, in particular in a vertebral body, of the patient. The screw head 41 comprises an engagement structure 42, which in this case comprises a Torx shape (Figure 3) and is used to screw in the implant screw using a suitable tool.

A tulip head 5 serves to attach and fix the implant screw 4 shown in Figure 2 to a connecting rod 3, thus forming a fastening element. The tulip head 5 comprises a rod receiving opening 51, which is open in the longitudinal direction on the side opposite the implant screw 4 and thus allows the connecting rod 3 to be inserted from this side.

A clamping part not shown in the figures is used to secure the tulip head 5 to the connecting rod 3, wherein this clamping part comprises an external thread and can be screwed into an internal thread 52 in the tulip head 5. The connecting rod 3 inserted into

the rod receiving opening 51 can thus be clamped between the clamping part and the tulip head 5. The implant screw 4 can thus be attached and fixed to the connecting rod 3 by means of the tulip head 5 and the clamping part. The screw head 41 of the implant screw 4 is arranged inside the tulip head 5, as is well known from the prior art.

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In the embodiment shown in Figure 2, the tulip head 5 is designed in two parts with a main part 54, which forms the rod receiving opening 51, and a ring marker 53, which can be screwed onto the main part 54. When fully assembled, the screw head 41 of the implant screw 4 is located in an area of the tulip head 5 bounded by the main part 54 and the ring marker 53. The ring marker 53 thus also serves in particular to secure and lock the implant screw 4 to the tulip head 5. The ring marker 53 can therefore also be referred to as a locking ring. A cross-sectional view of the tulip head 5 with the screw-on ring marker 53 is shown in Figure 7. As can be clearly seen there, the main part 54 of the tulip head 5 and the ring marker 53 together form an inner space with rounded boundary surfaces for receiving the screw head 41. Before the connecting rod 3 is inserted, the engagement structure 42 is accessible through the tulip head 5 (Figure 3).

The screw head 41 and the threaded shaft 43 are integrally formed and made of the same material, wherein the material is a radiolucent plastic material. Preferably, a fiber-reinforced composite material, such as preferably carbon fiber-reinforced PEEK, is used as the plastic material. The fibers preferably run along the longitudinal direction of the threaded shank 42 and advantageously have a length that is greater than the longitudinal extension of the implant screw 4.

25 A marker is inserted into the threaded shaft 43 at the tip S of the screw, which has a sleeve-shaped design here and is therefore referred to as a sleeve marker 45.

The ring marker 53 and the sleeve marker 45 are made of a material that is significantly more radiopaque than the plastic material of the implant screw 4. In imaging procedures, i.e., in particular in X-ray images and in computed tomography (CT), the ring marker 53 and the sleeve marker 45 thus show a clear contrast to other parts of the implant 2, in particular to the screw head 41 and to the threaded shaft 43, as well as to the surrounding tissue, wherein the ring marker 53 and the sleeve marker 45 are well recognizable in the

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imaging. In particular, the markers 53 and 45, which are clearly visible in the images provided, enable the position and orientation of the implant screw 4 in the patient's body to be determined accurately. Since the tulip head 5 comprises the ring marker 53 and this is firmly fixed to the main part 54, the position of the tulip head 5 and the inclination of the
 5 implant screw 4 relative to this (and thus to the connecting rod 3) can also be determined on the basis of the markers 53 and 45 shown. As can be seen from a comparison of Figures 2 and 7, when fully assembled, the ring marker 53 is positioned so that its ring center corresponds exactly to the center of the spherical screw head 41.

10 When the implant 2 is fully assembled, the washer 6 is positioned between the screw head 41 and the connecting rod 3. The ring-shaped washer 6 can serve to transfer the clamping force exerted by the clamping part to the screw head 41. The connecting rod 3 is then pressed by the clamping part onto the washer 6, which in turn presses the screw head 41 against the ring marker 53 designed as a locking ring. Alternatively, the washer 6 can also
 15 be used to decouple the clamping forces exerted by the clamping part on the one hand and by the ring marker 53 designed as a locking ring on the other hand, so that the tulip head 5 can be fastened independently and with different clamping forces to the connecting rod 3 and to the implant screw 4.

20 Depending on the embodiment, the clamping part and/or the washer 6 can be made of a radiolucent plastic material or of a radiopaque material, for example a metal such as preferably tantalum or titanium. If the clamping part and/or the washer 6 are made of a radiopaque material, they can help determine the position and location of the implant screw 4 in imaging procedures. The main part 54 of the tulip head 5 is preferably made in one
 25 piece and from a radiolucent plastic material, such as carbon fiber reinforced PEEK.

Figure 4 shows an embodiment of an implant screw 4 designed as a pedicle screw with a marker inserted into the screw tip S, which is referred to as a ball marker 44 due to its spherical design. The spherical design results in a point-shaped image of the marker with
 30 high contrast in the imaging process.

Figure 5 shows a further embodiment which differs from that of Figure 4 in that the implant screw 4 is cannulated, i.e. it has a through channel extending in the longitudinal

direction for supplying, for example, medication or bone cement. In order to continue to enable delivery along the longitudinal direction through the screw tip S, a sleeve marker 45 is inserted at the screw tip S instead of a ball marker 44 as in the embodiment of Figure 4.

- 5 As can be clearly seen in Figures 4 and 5, the markers 44 and 45 arranged on the threaded shaft 43 are each located directly on the main longitudinal center axis H of the implant screw 4. Similarly, the ring center formed by the ring marker 53 is located directly on the main longitudinal center axis H.
- 10 Figures 6a and 6b show the polyaxial pivotability of the implant screw 4 relative to the tulip head 5. The pivotability is achieved by the tulip head 5 and the screw head 41 being connected to each other in a ball-and-socket manner. By tightening the clamping part only slightly or not at all during the first step of implanting the implant 2, the tulip head 5 with the connecting rod 3 inserted therein can still be moved, i.e., pivoted polyaxially relative to
- 15 the implant screw 4, even when the implant screw 4 is already firmly anchored. Only after the clamping part is tightened in a second step is the connecting rod 3 firmly, i.e. immovably, fixed to the implant screw 4 via the tulip head 5. After tightening the locking ring formed by the ring marker 53, the ring center of the ring marker 53 is located inside the screw head 41 and even corresponds to its center and thus to the pivot point of the
- 20 implant screw 4. Thereby, the position of the implant screw 4 relative to the tulip head 5 and thus to the connecting rod 3 can be intuitively recognized and precisely determined using imaging techniques.

As already mentioned, Figure 7 shows a variant of the tulip head 5 with a screw-on ring marker 53. Figure 8 shows another variant in which the ring marker 53 is screwed into the

25 main part 54 of the tulip head 5. Of course, other variants are also conceivable. For example, the ring marker 53 could also be applied in the form of a coating on a tulip head made in one piece.

- 30 Figure 9a schematically shows a circular cone K spanned by the ring marker 53 arranged on the tulip head 5 and the ball or sleeve markers 44 and 45, respectively, arranged on the screw tip S of the implant screw 4. Figure 9b shows the same circular cone K, but from a different angle than in Figure 9a. Due to the viewing angle, it can be seen here that the

circular cone K in three-dimensional space is actually an oblique cone, which indicates an inclination of the implant screw 4 relative to the tulip head 5 (e.g., as in Figure 6b). Based on the knowledge of the spatial positions of the screw tip S and the ring center M formed by the ring marker 53, the connecting line drawn as a dashed line in Figures 9a and 9b can be derived, which corresponds to the main longitudinal center axis H of the implant screw 4 and thus indicates the spatial position of the implant screw. The main longitudinal center axis H runs from the screw tip S always centrally through the screw head 41 and through the ring center point M of the ring marker 53. The orientation of the implant screw 4 can thus be clearly determined using the markers.

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Figure 10a schematically shows the dimensions in the direction of the longitudinal center axis of the tulip head 5 (x-y plane), as they can be presented, for example, in a two-dimensional CT image. The imaging technique shows the ring marker 53 with the ring center M and the radius r, as well as the point-shaped ball marker at the tip of the screw S. Figure 10b schematically shows the same arrangement as in Figure 10a, but from a different viewing or recording angle, here perpendicular to the longitudinal center axis of the tulip head 5 (y-z plane). The dimensions a and b shown are perpendicular to each other, as are the dimensions c and d. Therein, the dimensions b and c have the same values. Using two images taken using the imaging method according to Figures 10a and 10b, trigonometric calculations based on the measured distances a, b, c, d, m can be used to easily calculate and precisely determine, for example, the angle of the main longitudinal center axis H of the implant screw 4 relative to the tulip head 5. The two images can be taken from any direction, but preferably from directions that are 90° apart.

Due to the known arrangement of the ring center M in the pivot point or in the pivot axis of the implant screw 4, the position of the implant screw 4 relative to the tulip head 5 and thus to the connecting rod 3 can be intuitively recognized and precisely determined in the imaging process.

Figure 11 shows the same illustration as in Figure 10b, but the implant screw 4 has changed its inclination relative to the tulip head 5, so that the screw tip S is now located at a new position of the screw tip S'. The angle of the main longitudinal center axis H of the implant screw 4 relative to the tulip head 5 can again be calculated using two images and

used to verify the stability of the interlock between the tulip head 5 and the implant screw 4.

Figure 12 illustrates a method according to the invention for planning the radiation in medical radiation therapy based on radiopaque ball markers 44, each of which is attached to the tip of the threaded shaft 43 of an implant screw 4. The volume to be irradiated is formed here by a tumor T located directly on the spine. Instead of ball markers 44, sleeve-shaped or any other shape of marker could be used.

Due to the anchoring of the implant screws 4, which are preferably made of a fiber-reinforced plastic material, in each vertebral body W, the radiopaque ball markers 44 can be used in an imaging procedure as a particularly precise and reliable spatial reference for planning the therapeutic irradiation. The patient, who already has the implant screws 4 in place, therefore does not have to undergo a further medical procedure to insert position markers for the radiation therapy.

Using an imaging technique, the ball markers 44 can thus be used to establish a spatial three-dimensional reference system x, y, z with which the position of the area of the body and, in particular, of the tumor T is determined, which is irradiated therapeutically by means of an irradiation device 7. The ball markers 44 at the tip of the implant screws 4 thus serve as reference points for positioning the patient for irradiation and during “image-guided” radiotherapy. This is made possible in particular by the defined and always consistent geometric shape of the markers.

LIST OF REFERENCE SIGNS

1	pedicle system		
2	implant	6	washer
3	connecting rod		
4	implant screw	7	radiation device
41	screw head		
42	latching structure	W	vertebral body
43	threaded shaft	B	intervertebral disc
44	spherical marker	T	tumor
45	sleeve marker		
		H	main longitudinal center axis
5	tulip head	S, S'	screw tip
51	rod reception opening	M	center point of ring
52	internal thread	r	radius
53	ring marker	K	circular cone
54	main part		

CLAIMS

1. Medical implant (2) with an implant screw (4), in particular a pedicle screw,
5 which comprises a screw head (41) and a threaded shaft (43) and is made of a plastic material,

wherein the implant (2) comprises radio-opaque markers (44; 45, 53) to allow the spatial position of the implant screw (4) to be determined in an imaging procedure,

10 characterized in that

one of the markers (53) or several of the markers together form a ring with a ring center (M) located inside the screw head (41), and that a further marker (44; 45) is located on or inside the threaded shaft (43).
- 15 2. Implant according to claim 1, wherein the marker (44; 45) arranged on or in the threaded shaft (43) is arranged in the last third of the threaded shaft (43) along a longitudinal direction extending from the screw head (41) to a free end (S) of the threaded shaft (43).
- 20 3. Implant according to claim 2, wherein the marker (44; 45) arranged on or in the threaded shaft (43) is arranged at the free end (S) of the threaded shaft (43).
4. Implant according to one of the preceding claims, wherein the implant (2) comprises a fastening element (5) for attaching, especially securing the implant screw (4), preferably to a connecting rod (3), and wherein the fastening element
25 (5) comprises the one or more marker(s) (53) forming a ring.
5. Implant according to claim 4, wherein the marker or markers (53) forming a ring are formed by a screw element that can be screwed onto the fastening element (5).

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6. Implant according to claim 5, wherein the screw element serves to hold the implant screw (4) on the fastening element (5).

7. Implant according to one of claims 4 to 6, wherein the implant screw (4) attached to the fastening element (5) can be pivoted with the threaded shaft (43) relative to the fastening element (5) in a polyaxial manner about the ring center point (M).
- 5 8. Implant according to one of the preceding claims, wherein the marker (44) arranged on or in the threaded shaft (43) is spherical in shape.
9. Implant according to one of claims 1 to 7, wherein the marker (45) arranged on or in the threaded shaft (43) is ring-shaped and the implant screw (4) is preferably cannulated.
- 10 10. Implant according to one of the preceding claims, wherein the ring formed by the one or more markers (53) comprises an inner diameter that is larger than an outer diameter of the screw head (41).
- 15 11. Implant according to one of the preceding claims, wherein the ring center point (M) is located on the main longitudinal center axis (H) of the implant screw (4).
12. Implant according to one of the preceding claims, wherein the marker (45) arranged on or in the threaded shaft (43) forms a center point which is located on the main longitudinal center axis (H) of the implant screw (4).
- 20 13. Implant according to one of the preceding claims, wherein the markers (44; 45, 53) are each made of a metal, in particular of tantalum or titanium.
- 25 14. Implant according to one of the preceding claims, wherein the plastic material of the implant screw (4) is a thermoplastic plastic material, preferably polyetheretherketone, more preferably polyetheretherketone (PEEK).
- 30 15. Implant according to one of the preceding claims, wherein the plastic material of the implant screw (4) is fiber-reinforced, in particular carbon fiber-reinforced.
16. Method for planning the radiation in medical radiation therapy, in which one or

more radio-opaque markers (44; 45) are used in an imaging procedure as a spatial reference for planning the therapeutic radiation of a human or animal patient, the one or more markers being attached to or inside the patient's body,

characterized in that

5 the one or more markers (44; 45) are each arranged on or in the threaded shaft (43) of an implant screw (4), preferably of a pedicle screw and particularly preferably of an implant screw (4) of a medical implant according to one of the preceding claims, which is made of a plastic material and is anchored in the body, preferably in a bone, of the patient.

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