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We, the undersigned, Parleclair, 1-3 bld Charles de Gaulle, 92707 Colombes, hereby certify that we are duly authorized to translate the French language, and have produced an accurate and exact translation in English of the French Patent PCT/FR05/02143 to the best of our translators' knowledge and skill.

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A handwritten signature in black ink, consisting of a series of loops and a long horizontal stroke extending to the right.

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Implant comprising one or more electrodes and associated
insertion instrument

The present invention relates to the field of general orthopaedics and, more particularly, to the insertion of
5 implants, in particular implants such as screws, pins, etc., for placing devices that allow, for example, vertebral column correction and stabilisation or fracture reduction.

Such implants are designed to be positioned in the bone structure.

10 One of the main difficulties practitioners find when inserting these implants is managing to position them correctly.

While incorrect positioning of the implant may not result in a satisfactory therapeutic result, it can also cause pain,
15 paralysis, haemorrhages, etc. in the patient, which often require further surgical operations, or in certain cases can even cause irreparable damage.

It therefore becomes necessary for the practitioner to be able, not only to follow, but also to guide the implant
20 during its insertion.

The prior art already knows devices that make it possible to follow the penetration of an instrument in an anatomical structure, in particular a bone structure.

In particular, patent application FR2835732, filed by the
25 present applicant, is known to provide a device that makes it possible to follow the penetration of a drilling instrument in the vertebra by measuring electrical impedance differences during penetration, so that the practitioner can know, at all times, whether the tip of the instrument comes
30 out of the bone cortex and penetrates a soft tissue area

(marrow, nerves, tissue). In this case, the practitioner can modify the path of the penetration instrument to return to the bone cortex. Such a device makes it possible, therefore, to detect the formation of a crack in the bone cortex at the time of drilling the pre-drilling hole. For this purpose, said follow-up device set forth in the patent application comprises at least one electrostimulator capable of providing neuromuscular stimulation, which can be connected to at least two electrodes, at least one of which is located at one distal end of the drilling instrument, at least one inductometer connected to at least two electrodes, at least one of which is located at a distal end of the drilling instrument, and at least one signalling device capable of producing a signal in the event that the inductometer detects a change in the impedance.

Such a device does not, however, make it possible to follow up the insertion of an implant in the pre-drilling hole.

The present invention aims to provide a piece of equipment that makes it possible to follow and guide an implant during its insertion in a bone structure, the latter being drilled directly by the implant during its insertion or during a previous operation.

For this purpose, the invention relates, in its broadest sense, to an implant intended to be inserted in an anatomical structure, in particular a bone structure.

The invention is notable in that said implant comprises at least two electrodes separated from one another by an insulator, said electrodes being flush with the surface of said implant so as to allow said implant to be followed up and guided during its insertion in the anatomical structure.

Said electrodes are preferably arranged so that:

i) one of the electrodes is at least partially flush with the peripheral surface of said implant,

ii) the other electrode is selectively flush with the peripheral surface of said implant.

5 Said electrodes are advantageously arranged so that:

i) one of the electrodes at least partially forms the peripheral surface of said implant,

10 ii) the other electrode, which is internal to said implant, is selectively flush with the distal surface of said implant.

With the implant thus configured, it is possible to follow its progress as it is inserted in the anatomical structure, when it is positioned using the adapted insertion instrument, which is described below.

15 The external electrode is preferably substantially tubular.

Likewise, said internal electrode is advantageously substantially tubular.

Said electrodes are advantageously coaxial or eccentric.

20 In a preferred embodiment of the invention, the electrode(s) can be removed.

Said insulation is advantageously also removable. In this case, it is removed simultaneously with said internal electrode or once the latter has been removed.

25 The present invention also relates to an implant not equipped with the previously described removable part, namely the internal electrode and, optionally, the insulation. In this case, the implant, which has a channel passing through it, comprises at least one electrode being

flush with at least a part of the peripheral surface of said implant, making up all or part of the lateral wall of said implant.

Said implant preferably consists of a tubular electrode.

5 Said implant advantageously comprises a tubular insulator.

Said channel advantageously passes through said implant longitudinally.

Said channel is advantageously a central channel.

10 The present invention also relates to an insertion instrument intended for inserting the previously described implants in an anatomical structure, in particular in an anatomical bone structure. For this purpose, said instrument is connected to a power source supplying at least two electrodes and to a means for measuring the impedance
15 between said electrodes.

In the case of an implant not equipped with the removable part as previously described, said instrument comprises an internal longitudinal part. This longitudinal part is designed to become housed in the channel of the implant.
20 Depending on whether or not the implant is equipped with an insulator, said longitudinal part consists of an electrode or an electrode surrounded by an insulator.

The longitudinal part of said instrument is advantageously removable. Thus, without the longitudinal part, said
25 instrument is adapted to be in contact with an implant which in turn comprises an internal electrode, separated from the external electrode by an insulator.

Said instrument advantageously comprises means allowing electrical contact with the electrode or electrodes when

said implant is in contact with said instrument. The electrical contact can be carried out internally and/or externally. Thus, for an internal contact, said insertion instrument comprises electrical contact elements positioned to be in contact with the internal electrode of the implant; for an external contact, said instrument comprises electrical contact elements positioned to be in contact with the peripheral electrode of said implant.

Said instrument advantageously comprises a cavity for receiving part of said implant, as well as means that allow said implant housed in said instrument to be centred.

Said insertion instrument advantageously comprises means for mechanically driving the implant.

With the implant and the instrument thus configured, it is then possible to follow the progress of the implant during its insertion in the bone structure by analysing an electric signal created by means of said electrodes.

When the distal end of the system, made up of the instrument and the implant, comes into contact with a crack formed in the bone structure, the impedance drops suddenly. With this information, the practitioner can rectify the path given to the implant in order to reposition it in the bone structure. The process continues in this way until the implant has been finally installed.

The invention will be understood better from reading the following description, provided for merely explanatory purposes, of a first embodiment of the invention, made in reference to the appended figures, wherein:

- figure 1 shows a cross-section view of an implant according to one embodiment of the invention;

- figure 2 shows a cross-section view of the implant of figure 1 having removed the removable part of said implant, as well as a cross-section view of the removable part removed from the implant;

5 - figure 3 shows a schematic view of an insertion instrument in contact with the implant of figure 1; and

- figure 4 shows a cross-section view of an implant according to a second embodiment of the invention, said implant being in contact with an insertion instrument.

10 Figure 1 shows a cross-section view of an implant (1) according to a first embodiment of the invention.

In this embodiment of the invention, the implant (1), such as a pedicle screw, has a threaded cylindrical body (2) having a pointed distal end (13), the other end being
15 equipped with a head (3). Evidently, the present invention is not limited to this implant configuration, which was chosen in this case for its simplicity and therefore to facilitate the description of the invention.

The body (2) of said implant (1) comprises two conductive
20 parts separated by an insulator (6).

More particularly, each of the conductive parts consists of an electrode (4, 5): a first electrode (4) forming the lateral wall of said implant (1) (external electrode) so that the external electrode is flush with the lateral
25 surface (17) and a part of the distal surface (18) of the body (2) of said implant (1); a second electrode (5) constituting an internal part of said implant ("internal electrode") and being selectively flush with the distal surface (18) of the body (2) of said implant (1).

The internal electrode (5), in the shape of a rod with a circular cross-section, advantageously passes through said implant (1). It is surrounded by the insulator (6), which in turn is surrounded by the external electrode (4).

- 5 According to a preferred embodiment of the invention, said electrodes (4, 5) are arranged so as to be coaxial. Evidently, this is a specific embodiment of the invention, it being understood that the body (2) of said implant (1) can consist, for example, of two eccentric electrodes.
- 10 In order to facilitate the electrical contact with an instrument intended for inserting such an implant (2) in a bone structure, the internal electrode (5) and the insulator (6) are extended through the head (3) of said implant (1).

- 15 According to a particularly advantageous embodiment of the invention, said implant (1) comprises a removable part (14). In this way, when the removable part (14) is removed, generally once the implant (1) has been positioned in the bone structure, a channel is formed in said implant (1) following its longitudinal axis (see figure 2).

- 20 The removable part (14) preferably comprises both the internal electrode (5) and the insulator (6). However, it is evident that those skilled in the trade will be able to plan for the removable part (14) of the implant (1) to consist only of the internal electrode (5), the insulator (6)
- 25 remaining in said implant (1) when said removable part (14) is removed.

- The removal of certain parts of the implant, such as the internal electrode and the insulator in the example described above, makes it possible to avoid leaving several
- 30 types of material implanted in the patient's body.

In addition, since only the materials that remain in the body of the patient must necessarily be so-called "implantable" materials, the parts of the implant removed once the latter is disposed in the bone structure can be made entirely from biocompatible materials. Since biocompatible materials are less expensive than implantable materials, an implant comprising a removable part will thus have the advantage of having a lower manufacturing cost than an implant that does not have a removable part.

Figure 3 shows a simplified view of the electrical contact between an instrument (11) for inserting an implant in a bone structure and the previously described implant (1). In order to simplify the figure, the real contact between said implant (1) and said instrument (11) has not been shown.

The electrical contact between the insertion instrument (11) and the implant (1) is provided by connection tabs (12, 19) which constitute said insertion instrument (11): an internal connection tab (19) being in contact with the internal electrode (5) of said implant (1) and at least one external connection tab (12) being in contact with the external electrode (4) of said implant (1).

In addition, since it is required to follow and guide the implant (1) during its insertion in the bone structure, the connection tabs (12, 19) of the insertion instrument (11) are connected to means for measuring the impedance between said electrodes (4, 5) (inductometer 20).

Said inductometer (20) can advantageously be connected to a warning device (not shown) that makes it possible to view the impedance variations measured between said electrodes (4, 5) by the inductometer (20). This can be, for example, a display screen that allows the follow-up, in the form of

curves, of variations in the impedance as the implant (1) penetrates in the bone structure.

Figure 4 shows a cross-section view of an implant (10) according to another embodiment of the invention and of an
5 insertion instrument (11) intended for placing said implant (10) in the bone structure.

In order to facilitate understanding of the principle of cooperation of the implant (10) with said instrument (11) and, in particular, to distinguish the elements that
10 respectively make up the insertion instrument (11) and said implant (10), this figure does not show the real cooperation between said implant (10) and said instrument (11).

In this example of an embodiment, said implant (10) consists of a threaded conductive body (2) having a pointed distal
15 end (13).

The tubular body (2) of said implant (10) is advantageously equipped with a channel (7) passing from one end of the body (2) of said implant (1) to the other.

The body (2) of said implant (10) is advantageously made up
20 of an electrode (4).

Said insertion instrument (11) intended for coming into contact with said implant (10) consists of a hollow body (8) equipped with a central longitudinal part (9), which is intended for becoming housed in the channel (7) of said
25 implant (10) when the latter is in contact with said instrument (11).

Said central longitudinal part (9) advantageously consists of an electrode (15) surrounded by an insulator (16). It is obviously evident that the longitudinal part (9) can consist
30 of only the electrode (15), the implant intended for coming

into contact with said insertion instrument (11) comprising its own insulator.

Thus, during its insertion in the bone structure, said implant (10) is fixed to the end of said instrument (11),
5 and the longitudinal part (9) of said instrument (11) is inserted in the channel (7) of said implant (10).

Electrical continuity is established in order to follow up the progress of the insertion of the implant (10).

The electrical contact is advantageously provided by means
10 of connection tabs (12) that come into contact with the electrode (4) constituting said implant (10).

Only the electrical part of the insertion instrument (11) that allows the follow-up and guiding of an implant in the bone structure has been presented. It is obviously evident
15 for those skilled in the trade that said insertion instrument (11) can comprise mechanical driving means which can be manual or such as an electric motor, which make it possible, for example, to drive the rotation, thrust, etc. of the implant.

20 The invention is described in the preceding paragraphs by way of an example. It is evident that a person skilled in the art will be capable of producing different variations of the invention without thereby departing from the context of the patent.

CLAIMS

1. Implant (1) intended for being placed in an anatomical structure, in particular a bone structure, characterised in that it comprises at least two electrodes (4, 5) separated by an insulator (6), said electrodes being flush with the surface of said implant (1) so as to allow said implant (1) to be followed up and guided during its insertion in the anatomical structure.
2. Implant (1) according to claim 1, characterised in that said electrodes (4, 5) are arranged so that:
- i) one of the electrodes (4) is at least partially flush with the peripheral surface of said implant (1),
 - ii) the other electrode (5) is selectively flush with the peripheral surface of said implant (1).
3. Implant (1) according to claim 1 or claim 2, characterised in that said electrodes (4, 5) are arranged so that:
- i) one of the electrodes (4) at least partially forms the peripheral surface of said implant (1),
 - ii) the other electrode (5), which is internal to said implant (1), is selectively flush with the distal surface of said implant (1).
4. Implant (1) according to claim 3, characterised in that the external electrode (4) is substantially tubular.
5. Implant (1) according to claim 3 or claim 4, characterised in that the internal electrode (5) is substantially tubular.

6. Implant (1) according to any one of the preceding claims, characterised in that said electrodes (4, 5) are coaxial.

7. Implant (1) according to any one of the claims from 1 to 5, characterised in that said electrodes (4, 5) are eccentric.

8. Implant (1) according to any one of the preceding claims, characterised in that the electrode(s) is(are) removable.

9. Implant (1) according to any one of the preceding claims, characterised in that said insulator (6) is removable.

10. Implant (10) intended for being placed in an anatomical structure, in particular a bone structure, characterised in that it comprises at least one electrode (5) being flush with at least a part of the peripheral surface of said implant (10) and in that it comprises a channel (7).

11. Implant (10) according to the preceding claim, characterised in that it consists of a tubular electrode (5).

12. Implant (10) according to claim 10 or claim 11, characterised in that it comprises a tubular insulator (6).

13. Implant (10) according to any one of the claims from 10 to 12, characterised in that the channel (7) passes through said implant (10) longitudinally.

14. Implant (10) according to any one of the claims from 10 to 13, characterised in that said channel (7) is central.

15. Insertion instrument (11) intended for inserting an implant (1) according to any one of the claims from 1 to 9 or an implant (10) according to any one of the claims 8 or 10 to 14 in an anatomic structure, in particular in an anatomical bone structure, said instrument (11) being

connected to a power source supplying at least two electrodes and to a means for measuring the impedance between said electrodes, characterised in that it comprises an internal longitudinal part (9) intended to be housed in the channel (7) of said implant (10), said longitudinal part (9) consisting of an electrode (15).

16. Instrument (11) according to the preceding claim, characterised in that said electrode (15) is surrounded by an insulator (16).

17. Instrument (11) according to claim 15 or claim 16, characterised in that the longitudinal part (9) of said instrument (11) is removable.

18. Instrument (11) according to any one of the claims from 15 to 17, characterised in that it comprises means allowing electrical contact with the electrode or electrodes (4, 5, 15) when said implant (1, 10) is in contact with said instrument (11).

19. Instrument (11) according to any one of the claims from 15 to 18, characterised in that it also comprises a cavity for receiving part of said implant (1, 10), as well as means that allow said implant (1, 10) housed in said instrument (11) to be centred.

20. Instrument (11) according to any one of the claims from 15 to 19, characterised in that it comprises means for mechanically driving the implant (1, 10).