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A5R RAP REHR

(56) Documents Cited

WO 2001/032262 A1	**WO 1998/022034 A2**
WO 1996/024406 A1	**US 5616140 A**
US 5445608 A	**US 4646743 A**

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(54) Abstract Title
METHOD AND APPARATUS FOR INTERACTING WITH BONE TISSUE USING ILLUMINATING RADIATION

(57) A device comprising an illuminating radiation source 3, and control means 4, to regulate the intensity and/or duration of the radiation emitted from the source which is internally implanted in tissue adjacent to the target bone and illuminating it in a controlled regime comprising at least one period of illumination. The radiation source may be LEDs or laser diodes and the wavelength may be in the range 400 nm-1000 nm and be emitted in pulses. The apparatus may comprise a power source 10, connected to the implanted radiation source. Other embodiments specify that the radiation source and control means are both implanted, or the radiation source, control and a power source be implanted. The implanted device may be powered by converting electromagnetic signals received 9, from outside the body 7, 8, into electricity. Methods of implanting and using the device are described.

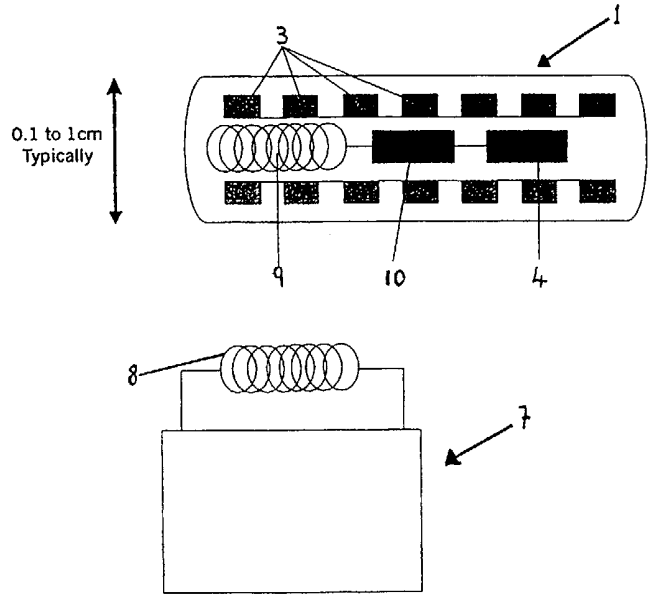

FIGURE 5

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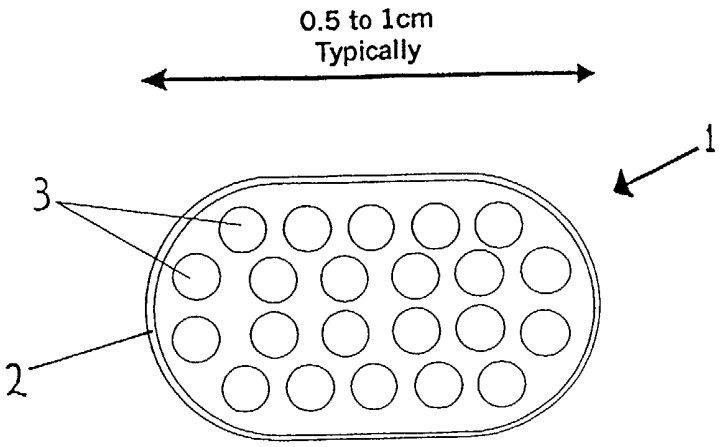

FIGURE 1

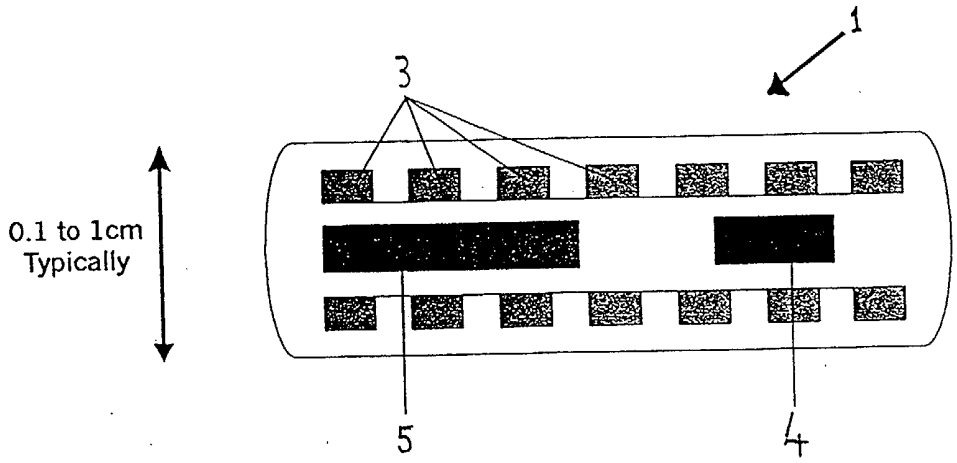

FIGURE 2

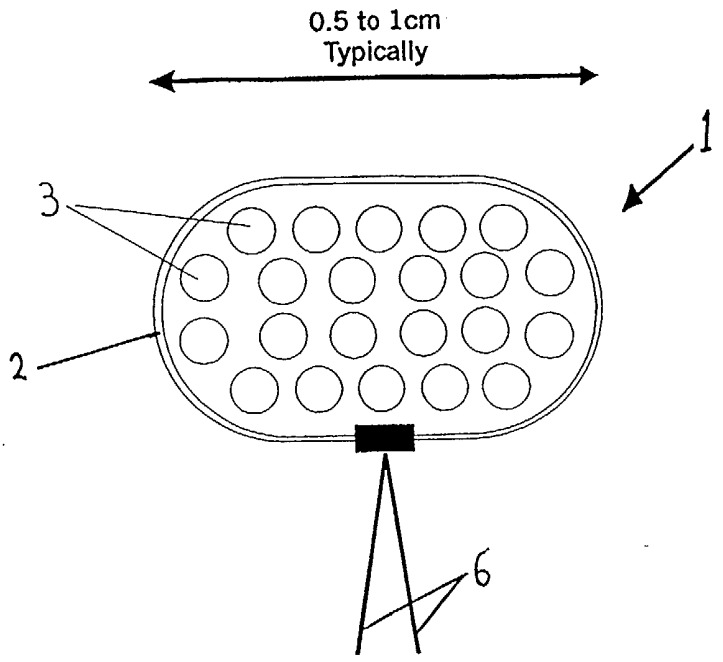

FIGURE 3

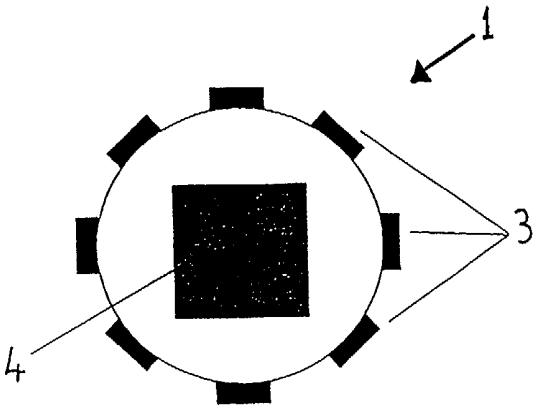

FIGURE 4

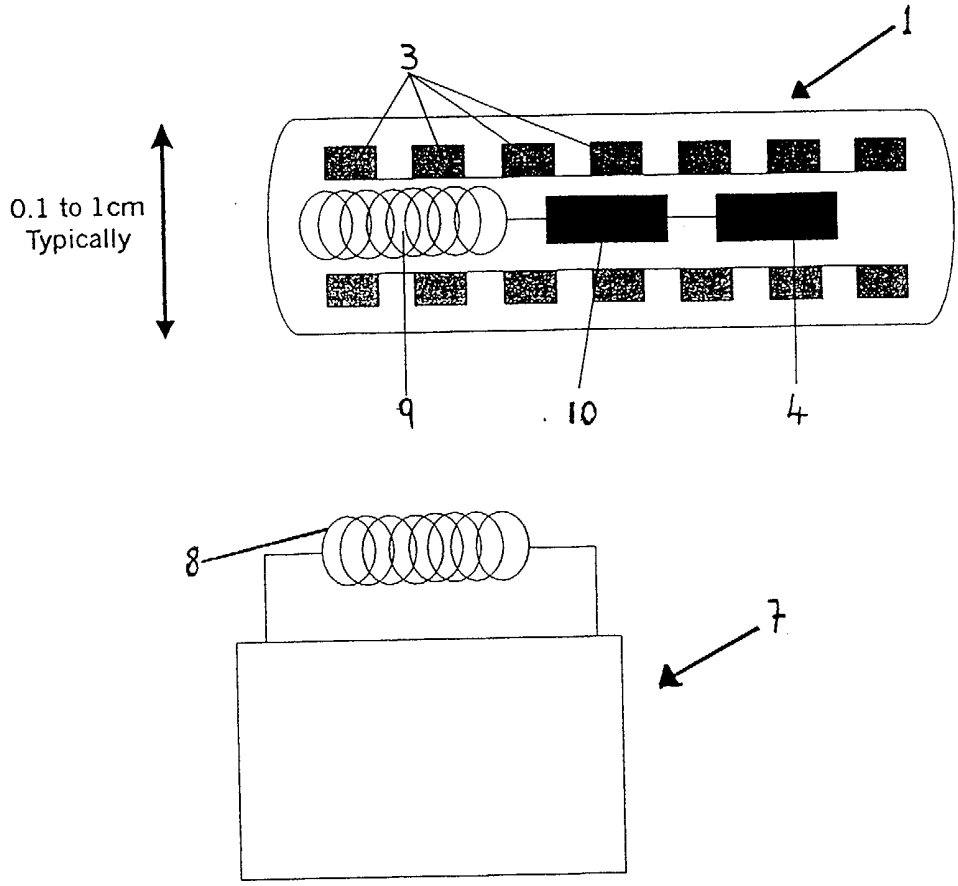

FIGURE 5

Method and apparatus for interacting with bone tissue using illuminating radiation

The present invention relates to a method and apparatus for interacting with bone tissue using illuminating radiation.

Many bone disorders, such as osteoporosis, lead to degradation of bone structure and strength. Thus, a treatment which results in new bone being formed at the treatment site may improve bone integrity and relieve disease symptoms.

Bone mainly consists of collagen and calcium deposits with an associated microvasculature blood supply. It is known that low doses of light, specifically visible or near infrared light, may induce an inflammatory response leading to an increase in the production of collagen by fibroblasts (collagen producing cells). Fibroblasts are typically triggered by mediators released by the vasculature which is generally stimulated by low doses of light.

Osteoblasts (bone producing cells) at a target zone of bone tissue when stimulated by illuminating radiation advantageously synthesise new bone tissue ideally improving the structure, strength and general integrity of bone at the target zone of bone tissue.

A trans-dermal delivery system, for example including a fibre optic cable or the like, may be used to deliver

illuminating radiation to a target zone of bone tissue. Surgical incision is usually necessary to insert the fibre optic cable in the vicinity of the bone tissue. The fibre optic cable is generally connected to an external source of illuminating radiation and acts as a means of delivering the illuminating radiation to the bone tissue.

Following completion of a period of illuminating radiation, the fibre optic cable is typically removed from the subjects body. It therefore follows that for each further period of illuminating radiation that may be required, surgical intervention is generally necessary which is time consuming, expensive and may lead to complications prevalent with any type of surgery.

An improved method of interacting with a target zone of bone tissue using illuminating radiation has now been devised.

According to the present invention there is provided a method of interacting with a target zone of bone tissue using illuminating radiation, which method comprises;

(i) providing apparatus comprising an illuminating radiation source and control means capable of controlling the intensity and/or duration of illuminating radiation emitted by the radiation source;

(ii) implanting the radiation source in tissue of a subject substantially in the vicinity of (preferably in or adjacent to) the target zone of

bone tissue, such that the radiation source is implanted substantially below the external surface of the subjects skin; and

(iii) controlling the intensity and/or duration of illuminating radiation emitted by the radiation source;

wherein the target zone of bone tissue is interacted with according to a controlled regime in which at least one period of illuminating radiation is emitted by the implanted radiation source.

The illuminating radiation source may be implanted on the surface of the target zone of bone tissue, or implanted within the bone tissue. Alternatively, the illuminating radiation source may be implanted in the vicinity of the target zone of bone tissue, for example, for anatomical areas whereby the target zone of bone tissue is surrounded by minimal internal biological tissue, the radiation source may be implanted in, adjacent to, or on the surface of the surrounding tissue provided the illuminating radiation emitted by the illuminating radiation source can penetrate through the surrounding tissue and stimulate osteoblasts in the target zone of bone tissue.

As the radiation source is implanted in the vicinity of the target zone of bone tissue, the bone tissue can advantageously receive more than one temporally spaced period of illuminating radiation emitted by the implanted radiation source without the need for further surgical intervention.

It is preferred that the controlled regime of interaction with the target zone of bone tissue comprises temporally spaced periods of illuminating radiation emitted by the implanted radiation source. The control means advantageously allows the radiation source to be activated and deactivated as and when required, according to the controlled regime.

The control means preferably enables a predetermined intensity and/or duration of illuminating radiation to be selected. The intensity and/or duration of illuminating radiation selected is ideally the optimum intensity and/or duration of illuminating radiation for osteoblast stimulation.

It is preferred that the illuminating radiation emitted by the radiation source is substantially in the range 400 nm to 1000 nm, preferably the illuminating radiation comprises a primary wavelength or narrow wavelength band substantially in the range 570 nm to 600 nm or 800 nm to 900 nm.

The illuminating radiation may be pulsed or continuous wave. Pulsed energy may be preferred in order to avoid overheating of the tissue in which the illuminating radiation source is implanted and may produce the optimum conditions for osteoblast stimulation. Pulse duration is preferably substantially in the range 0 to 0.5 seconds.

The present invention further provides apparatus for interacting with a target zone of bone tissue using illuminating radiation, which apparatus comprises an illuminating radiation source and control means capable of controlling the intensity and/or duration of illuminating radiation emitted by the radiation source, wherein the radiation source is dimensioned and configured to be implanted in tissue of a subject, such that the radiation source is implanted substantially below the external surface of the subjects skin.

The illuminating radiation source is preferably arranged to emit temporally spaced periods of illuminating radiation. The target zone of bone tissue can thus receive more than one temporally spaced period of illuminating radiation using apparatus of the present invention without the need for further surgical intervention.

The illuminating radiation source is preferably arranged to emit illuminating radiation substantially in or about the range 400nm to 1000 nm, preferably in the range 570 nm to 600 nm or 800 nm to 900 nm.

The illuminating radiation source preferably emits illuminating radiation at an energy density substantially in the range 0.5 J/cm^2 to 5 J/cm^2. The apparatus is preferably configured to inhibit output energies substantially above this range. Desirably, the apparatus (preferably the control means) is configured to permit variable selection of energy densities within the range.

The illuminating radiation source is preferably arranged to emit pulsed illuminating radiation with a pulse duration substantially in the range 0 to 0.5 seconds.

It is preferred feature of the present invention that the illuminating radiation source comprises a Light Emitting Diode (LED). Alternatively, other light emitters may be used, such as Laser Diodes. Beneficially, a plurality of light emitters are provided, preferably housed in a device housing and operable in concert and/or selectively individually or in sub-groups.

It is preferred that the radiation source is substantially inert so that the radiation source can be implanted into tissue of a subject for a prolonged period of time without inducing an immune response in the subject.

Apparatus of the present invention may include an implant device comprising the illuminating radiation source and at least one further element comprising a power supply system for the illuminating radiation source and/or a control system for the illuminating radiation source. The device is dimensioned and configured to be implanted in tissue of a subject, such that the device is implanted substantially below the external surface of the subjects skin.

The implant device is preferably substantially surrounded by a housing including at least a transparent portion. The housing is advantageously transparent to allow illuminating radiation emitted by the radiation source to pass through

the housing of the device and penetrate the target zone of bone tissue once the device has been implanted.

The implant device (at least the device housing) is preferably substantially inert so that the device can be implanted into tissue of a subject for a prolonged period of time without inducing an immune response in the subject.

The implant device may be substantially elongated and flattened. Alternatively the device may be substantially spherical. An elongated and flattened or spherical geometry advantageously allows maximum illumination angles.

Apparatus of the present invention preferably includes a power source. The power source generally powers the illuminating radiation source. The power source may also power the control means and other features which may be included in apparatus of the present invention.

The power source may be an external power source intended to remain outside a subjects body. Additionally or alternatively, an internal power source may be provided, for example, the implant device may include a power source such as a battery.

When an external power source is provided, the external power source may be connected to the implanted radiation source via one or more electrical connectors. It is therefore preferred in one embodiment that apparatus of the present invention includes an electrical connector arranged

to connect the radiation source to the power source.

A first electrical connector may be connected at one end to the illuminating radiation source, which radiation source is implanted in tissue of a subject. The opposing end of the first electrical connector may be implanted in the subjects skin. The end of the first connector implanted in the subjects skin can then be connected to the external power source via a second electrical connector.

Upon completion of a period of illuminating radiation emitted by the implanted illuminating radiation source, the second electrical connector can be disconnected from the first electrical connector. The first connector typically remains implanted in the subjects skin so that if further periods of illuminating radiation are required, the second connector can easily be reconnected to the first connector to provide power from the external power source to the implanted radiation source.

A remote control and/or power source or supply system may be used, typically comprising a respective power or control sub-unit respectively mounted on-board the implant device. An external power/control unit interacts with the device on-board sub-unit to power/control operation of the device.

An electromagnetic signal remote control system (for example, using Radio-frequency signals) may be employed in the present invention. Apparatus of the present invention may therefore include means for receiving electromagnetic

control signals (such as an antennae capable of receiving Radio-frequency signals). It is preferred that the signal receiving means is mounted on-board the implant device. Commands such as activate (operate), deactivate (render inoperable), output power, illuminating radiation wavelength, emission duration and the like can be encoded into such signals and transmitted to the signal receiving means from a remote control unit so as to control the intensity and/or duration of illuminating radiation emitted by the radiation source. The remote control unit may therefore include means for transmitting electromagnetic control signals (such as an antennae capable of transmitting radio-frequency signals).

When apparatus of the present invention includes means for receiving control signals from a remote controller unit as hereinbefore described, the apparatus may further include conversion means (preferably mounted on-board the implant device) capable of converting control signals received by the receiving means into electrical power. The electrical power generated by the conversion means may be used to power the radiation source, the control system or any other feature included in the apparatus of the present invention.

There is further provided by the present invention a method of setting up apparatus according to the present invention for interacting with a target zone of bone tissue using illuminating radiation, which method comprises implanting the illuminating radiation source or the implant device in tissue of a subject substantially in the vicinity of

(preferably in or adjacent to) the target zone of bone tissue, such that the radiation source or the device is implanted substantially below the external surface of the subjects skin.

The present invention further provides use of apparatus according to the present invention for interacting with a target zone of bone tissue using illuminating radiation. The illuminating radiation source or the implant device is implanted in tissue of a subject substantially in the vicinity of (preferably in or adjacent to) the target zone of bone tissue, such that the radiation source or the device is implanted substantially below the external surface of the subjects skin.

The present invention further provides use of a source of illuminating radiation in the manufacture of medicament implant apparatus for interacting with a target zone of bone tissue using illuminating radiation.

There is further provided by the present invention bone tissue with an illuminating radiation source implanted therein.

According to a further aspect, the present invention provides apparatus as hereinbefore defined for use in interacting with a target zone of bone tissue, the apparatus including an illuminating radiation source implanted in the vicinity of the target zone of bone tissue to be substantially below the surface of a subjects skin.

Apparatus for interacting with a target zone of bone tissue using illuminating radiation will now be further described in specific embodiments, and by way of example only, with reference to the accompanying drawings in which:

Figure 1 is a schematic plan view of an exemplary apparatus according to the invention;

Figure 2 is a schematic side view of an exemplary apparatus according to the invention;

Figure 3 is a schematic view of an alternative exemplary apparatus according to the invention;

Figure 4 is a schematic view of a further alternative apparatus in accordance with the invention; and

Figure 5 is a schematic view of a further alternative apparatus according to the invention together with a remote external controller and power source.

Referring to the drawings and initially to Figures 1 and 2, there is shown an implant device 1 with an optically transparent housing 2. Device 1 comprises a plurality of individual illuminating radiation emitters 3 (typically Light Emitting Diodes (LEDs) or Laser Diodes) positioned within transparent housing 2 (shown most clearly in Figure 2). The housing 2 of device 1 is transparent to enable illuminating radiation emitted by illuminating radiation emitters 3 to penetrate surrounding tissue which device 1

may be implanted therein. The illuminating radiation emitters 3 may be operated in unison, or individually, or in sub-groups.

Figure 2 shows a control system 4 and a power source 5 encased within the body of device 1. Power source 5 typically provides power to illuminating radiation emitters 3. Control system 4 typically controls the intensity and/or duration of illuminating radiation emitted by illuminating radiation emitters 3. For example, illuminating radiation emitters 3 are typically controlled to emit illuminating radiation in a pulsed regime in which the inter-pulse interval is sufficient to prevent overheating of the tissue.

Device 1 is preferably inert so that it can be implanted into tissue of a subject for a prolonged period of time without inducing an immune response in the subject. Device 1 can be flat and elongated as shown in Figures 1 and 2 or spherical as shown in Figure 4. The illuminating radiation emitters 3 shown in Figure 4 are not within the housing 2 of device 1 but are instead position on the surface of device 1.

Figure 3 shows an alternative apparatus according to the present invention where an external power source (not shown) is provided instead of, or in addition to, an internal power source. An external power source can be connected to device 1 via electrical connectors 6 which pass from device 1 to the surface of a subject's skin.

The electrical connectors 6 at the skin surface can be connected to an external power source via further connectors (not shown).

The apparatus shown in Figure 5 has a remote external controller 7 with transmitter 8 capable of transmitting electromagnetic control signals, such as Radio-frequency signals. The control signals transmitted by transmitter 8 can be received by receiver 9 positioned on-board device 1. Both transmitter 8 and receiver 9 may be antennae capable of transmitting and receiving Radio-frequency signals respectively. Receiver 9 is connected to a power converter 10 within the body of device 1. Power converter 10 can convert control signals received by receiver 9 into electrical power to power illuminating radiation emitters 3. Additionally or alternatively, control signals sent by controller 7 via transmitter 8, can be used to control the intensity and/or duration of illuminating radiation emitted by illuminating radiation emitters 3. Control signals are typically received by receiver 9 and transmitted to control system 4 to control illuminating radiation emitters 3. Commands such as activate/deactivate, output power, illuminating radiation wavelength and emission duration can be encoded into the control signals transmitted to receiver 9 and acted upon by control system 4.

CLAIMS:

1. A method of interacting with a target zone of bone tissue using illuminating radiation, which method comprises;

   (i) providing apparatus comprising an illuminating radiation source and control means capable of controlling the intensity and/or duration of illuminating radiation emitted by the radiation source;

   (ii) implanting the radiation source in tissue of the subject substantially in the vicinity of the target zone of bone tissue, such that the radiation source is implanted substantially below the external surface of the subjects skin; and

   (iii) controlling the intensity and/or duration of illuminating radiation emitted by the radiation source;

   wherein the target zone of bone tissue is interacted with according to a controlled regime in which at least one period of illuminating radiation is emitted by the implanted radiation source.

2. A method according to claim 1, wherein the radiation source is implanted substantially in or adjacent to the target zone of bone tissue.

3. A method according to claim 1 or 2, wherein the controlled regime of interaction with the target zone of bone tissue comprises temporally spaced periods of

illuminating radiation emitted by the implanted radiation source.

4. A method according to any preceding claim, wherein the illuminating radiation emitted by the radiation source is of a predetermined wavelength, preferably corresponding to the optimum wavelength for osteoblast stimulation.

5. A method according to any preceding claim, wherein the illuminating radiation emitted by the radiation source is substantially in the range 400 nm to 1000 nm.

6. A method according to claim 5, wherein the illuminating radiation comprises a primary wavelength or narrow wavelength band substantially in the range 570 nm to 600 nm or 800 nm to 900 nm.

7. A method according to any preceding claim, wherein the illumination radiation emitted by the illuminating radiation source is pulsed.

8. A method according to claim 7, wherein the pulse duration is substantially in the range 0 seconds to 0.5 seconds.

9. Apparatus for interacting with a target zone of bone tissue using illuminating radiation, which apparatus comprises an illuminating radiation source and control means capable of controlling the intensity and/or

duration of illuminating radiation emitted by the radiation source, wherein the radiation source is dimensioned and configured to be implanted in tissue of a subject, such that the radiation source is implanted substantially below the external surface of the subjects skin.

10. Apparatus according to claim 9, wherein the illuminating radiation source is arranged to emit temporally spaced periods of illuminating radiation.

11. Apparatus according to claims 9 or 10, wherein the illuminating radiation source comprises a Light Emitting Diode (LED) and/or Laser Diode.

12. Apparatus according to any of claims 9 to 11, wherein the radiation source is substantially inert.

13. Apparatus according to any of claims 9 to 12, wherein the illuminating radiation source is arranged to emit illuminating radiation substantially in or about the range 400 nm to 1000 nm.

14. Apparatus according to claim 13, wherein the illuminating radiation source is arranged to emit illuminating radiation substantially in or about the range 570 nm to 600 nm or 800 nm to 900 nm.

15. Apparatus according to any of claims 9 to 14, wherein the illuminating radiation source is arranged to emit

illuminating radiation at an energy density substantially in the range 0.5 J/cm^2 to 5 J/cm^2.

16. Apparatus according to any of claims 9 to 15, wherein the illuminating radiation source is arranged to emit illuminating radiation in a pulsed wave with a pulse duration substantially in the range 0 seconds to 0.5 seconds.

17. Apparatus according to any of claims 9 to 16, including a power source.

18. Apparatus according to claim 17, including an electrical connector arranged to connect the radiation source to the power source.

19. Apparatus according to any of claims 9 to 18, including a device comprising the illuminating radiation source and at least one further element comprising a power supply system for the illuminating radiation source and/or control system for the illuminating radiation source, which device is dimensional and configured to be implanted in tissue of a subject such that the device is implanted substantially below the external surface of the subjects skin.

20. Apparatus according to claim 19, wherein the device is substantially surrounded by a housing including at least a transparent portion.

21. Apparatus according to claim 20, wherein the housing of the device is substantially inert.

22. Apparatus according to any of claims 19 to 21, wherein the device is substantially elongated and flattened.

23. Apparatus according to any of claims 19 to 21, wherein the device is substantially spherical.

24. Apparatus according to any of claims 19 to 23, wherein the device includes means for receiving electromagnetic signals (such as Radio-frequency signals).

25. Apparatus according to claim 24, wherein the device further includes conversion means arranged to convert electromagnetic signals received by the signal receiving means into electrical power.

26. A method of setting up apparatus according to any of claims 9 to 18 for interacting with a target zone of bone tissue using illuminating radiation, which method comprises implanting the illuminating radiation source in tissue of a subject substantially in the vicinity of (preferably in or adjacent to) the target zone of bone tissue, such that the radiation source is implanted substantially below the external surface of the subjects skin.

27. A method of setting up apparatus according to any of claims 19 to 25, for interacting with a target zone of bone tissue using illuminating radiation, which method comprises implanting the device in tissue of a subject substantially in the vicinity of (preferably in or adjacent to) the target zone of bone tissue, such that the device is implanted substantially below the external surface of the subjects skin.

28. Use of apparatus according to any of claims 9 to 18, for interacting with a target zone of bone tissue using illuminating radiation.

29. Use according to claim 28, wherein the illuminating radiation source is implanted in the tissue of a subject substantially in the vicinity of (preferably in or adjacent to) the target zone of bone tissue, such that the radiation source is implanted substantially below the external surface of the subjects skin.

30. Use of apparatus according to any of claims 19 to 25, for interacting with a target zone of bone tissue using illuminating radiation.

31. Use according to claim 30, wherein the device is implanted in tissue of a subject substantially in the vicinity of (preferably in or adjacent to) the target zone of bone tissue, such that the device is implanted substantially below the external surface of the

subjects skin.

32. Use of a source of illuminating radiation in the manufacture of medicament implant apparatus for interacting with a target zone of bone tissue using illuminating radiation.

33. Bone tissue with an illuminating radiation source implanted therein.

34. Apparatus for use in interacting with a target zone of bone tissue, which apparatus includes an illuminating radiation source implanted in the vicinity of the target zone of bone tissue, to be substantially below the surface of a subjects skin.

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Application No: GB 0115737.9
Claims searched: 9-25 and 32
Examiner: Dr R.A. Lewis
Date of search: 10 January 2002

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.T): A5R (REHR), (RAP)

Int Cl (Ed.7): A61B18/18, A61B18/20, A61N5/06

Other: Online PAJ/WPI/EPODOC

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
A	WO 01/32262 A1	(PASSY) see whole document	
X	WO 98/22034 A2	(BOSTON SCIENTIFIC CORPORATION) see pages 3-4; page 6 line 1 - page 10 line 16; page 14 line 20 - page 16 line 30 and Figures.	9, 11, 12, 17, 18
X	WO 96/24406 A1	(QUANTUM DEVICES INC) see whole document	9, 11-13, 17, 18
A	US 5616140 A	(PRESCOTT) see whole document.	
X	US 5445608 A	(CHEN) see whole document and in particular column 3 line 56- column 5 line 45; column 9 line 18-column 10 line 45; column 11 lines 46-50; column 12 lines 44-49; column 17 lines 1-48; column 18 line 20-24; column 21 lines 44-50 and Figures	9-12, 17-21, 23-25 and 34
X	US 4646743	(PARRIS) see column 2 line 28-column 4 line 23 and Figures.	9-12, 14

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.