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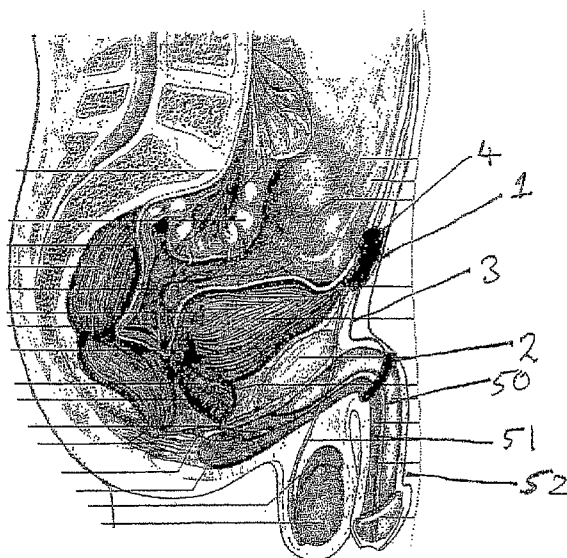
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ning of each regular issue of the PCT Gazette.

(54) Title: A METHOD AND APPARATUS FOR MANAGING ERECTILE DYSFUNCTION



(57) Abstract: The present invention relates to an apparatus and method for treating erectile dysfunction. One of the causes of erectile dysfunction is venous leakage, where one or more veins carrying the blood from the penis are unable to retain sufficient blood within the penis to maintain erection. Embodiments of the present invention propose implanting contractile tissue sphincters around the base of the penis and/or around one or more veins, and stimulating the contractile tissue to contract when an erection is required to be maintained. Stimulation is provided by an implantable stimulator.

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A METHOD AND APPARATUS FOR MANAGING ERECTILE DYSFUNCTION

US patent number 6659936 issued on 9 December 2003,
International Patent Application No. PCT/AU00/00925 filed
5 on 4 August 2000, Australian Provisional Application AU
PQ2026 filed on 4 August 1999, relate to the control of
urinary incontinence.

International Patent Application No.
PCT/AU2005/001698 filed on 8 November 2005, Australian
10 Provisional Application No. AU2004906393 filed on 8
November 2004, relate to an implantable electrode
arrangement.

International Patent Application No.
PCT/AU2006/001301 filed on 4 September 2006, Australian
15 Provisional Application No. AU2005904830, filed on 2
September 2005, relate to an implant for managing a
medical condition.

Australian Provisional Application No. 2006902107
filed 24 April 2006 relate to a method and apparatus for
20 managing erectile dysfunction.

International Patent Application No.
PCT/AU2006/000258 filed on 2 March 2006, Australian
Provisional Application No. 2005900957 filed on 2 March
2005, relate to an improved method and device for managing
25 urinary incontinence.

Each one of the above documents are incorporated
herein by reference in their entirety.

Field of the Invention

30 The present invention relates to a method and
apparatus for facilitating erection and, more
particularly, but not exclusively, to a method and
apparatus for managing erectile dysfunction.

35 Background of the Invention

Erectile dysfunction (commonly known as "impotence")
is a common condition. There are number of different

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causes, some more treatable than others. It is known, for example, that one cause of erectile dysfunction is an inability for blood supply to the penis to initiate and/or maintain an erection. In some cases this may be treated
5 with pharmaceuticals arranged to promote blood supply to the penis e.g. sildenafil.

While a number of conditions may be responsive to blood supply promoters, not all causes of erectile dysfunction will be. Where a major artery (e.g. the deep
10 artery or dorsal artery or both) is occluded, for example, then blood supply promoters will not be effective or wholly effective. Further, where venous leakage is occurring, blood supply promoters may not be effective in maintaining an erection.

15 In such cases it may be possible to treat the condition by penile vascular surgery. The success rate for penile vascular surgery (particular long term) is low, however. The selection criteria for appropriate patients is also fairly severe, so that the number of patients who
20 are determined to be suitable for surgery is also low. In the case of massive venous leakage (where many blood vessels are leaking blood from the penis) the surgery will generally be ineffective and patients with this condition are not selected for vascular surgery. In addition, as
25 the surgery involves permanent or partial occlusion of blood vessels and or surrounding tissue to slow venous leakage, subsequent atrophy and tissue damage may occur, or the formation of collateral circulation, either of which may reduce the effectiveness of the penile vascular
30 surgery.

In an earlier patent application, International Patent Application No. PCT/AU00/00925 (referred to above), a method and apparatus is proposed for treating urinary incontinence which includes the steps of forming a
35 "neosphincter" from smooth muscle tissue taken from elsewhere in the patient's body, and wrapping the neosphincter around the urethra. An implantable

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stimulator provides an electrical signal to the neosphincter via an electrode or electrodes. The electrical signal stimulates the neosphincter to maintain tone about the urethra to reduce leaks from the bladder
5 until the user wishes to urinate. A signal from a control device may cause the stimulator to stop providing the electrical signal to the neosphincter, to allow the neosphincter to relax and enable the individual to urinate. The stimulation may activate the muscle
10 directly, or activate it through the excitation of nerve fibres that innervate the muscle.

Summary of the Invention

In accordance with a first aspect, the present
15 invention provides an apparatus for facilitating an erection in a patient, the apparatus including a stimulator arranged to provide a signal for stimulation of contractile tissue, in order to facilitate an erection.

In an embodiment, the contractile tissue is
20 positioned proximate the penis and on activation is arranged to constrict one or more blood vessels and/or the cavernosal bodies in order to facilitate retention of blood in the penis and the promotion/maintenance of an erection. The contractile tissue may be implanted about
25 the penis (under the skin) around the cavernosal bodies so that on constriction it constricts the cavernosal bodies and blood vessel(s), such as the dorsal vein. The contractile tissue may be in the form of a ring about the penis. Alternatively or additionally, the contractile
30 tissue may be placed about one or more blood vessels e.g. the dorsal vein and may be in the form of a small "wrap" about the one or more blood vessels. The contractile tissue may be placed at the root of penis or may be placed internally further back about the left and right crura.
35 In an embodiment, the erection is facilitated by the contraction of the contractile tissue maintaining the retention of blood in the penis, so that once blood has

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flowed into the penis, it does not flow out at such a rate that the erection fails.

In an embodiment, the contractile tissue may have properties the same as or similar to smooth muscle tissue.

5 In an embodiment, the contractile tissue is smooth muscle tissue. In an embodiment, the sphincter or wrap may be formed from the dartos muscle or from a conveniently located portion of vein from the patient. In an embodiment, the sphincter or wrap may be formed from
10 muscle from the wall of the gastro-intestinal tract. In an embodiment, the smooth muscle tissue may be transplanted tissue taken from a donor, from elsewhere in the patient's body, or may have been grown externally.

In an embodiment, the signal provided by the
15 stimulator is in the form of a pulse signal, arranged to maintain tone in the contractile tissue.

In an embodiment, the stimulator is arranged to provide a different stimulation signal or no stimulation signal, in order to allow the contractile tissue to relax.
20 A controller, operable by the patient, may be provided to vary the stimulation signal.

In an embodiment, the signal is arranged to stimulate the contractile tissue through stimulation of nerve fibres innervating the contractile tissue by means of an
25 implantable electrode.

An advantage of an embodiment of the invention is that it may be effective to facilitate erection in cases of venous leakage, and even massive venous leakage, which is presently practically untreatable. Further, there will
30 generally be no requirement for complex vascular surgery (e.g. joining blood vessels to each other). Further, unlike vascular surgery, when the patient does not wish to have an erection, the stimulation may be reduced or turned off to the contractile tissue, causing it to relax so the
35 venous blood outflow from the penis is unimpeded. Additionally, in an embodiment, the patient or supervising clinician can vary the stimulation to the contractile

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tissue and thus conveniently adjust the extent of constriction applied by the contractile tissue. This may be able to provide more effective therapy as the patient's needs change due to response to surgery, age or changes in pharmacological regime. Further, unlike penile implants which require mechanical transfer of fluid by using a small hand pump in the scrotum, one advantage of at least an embodiment of this invention is that there is no mechanical manipulation of the delicate skin of the scrotum, risking erosion and or infection. Further, rather than penile implants which add significant bulk to the penis even when flaccid, making them uncomfortable and awkward, in at least an embodiment of this invention it is intended that there be only little bulk implanted in the penis, being the stimulation electrode and the wrap of contractile tissue, so that the penis can be allowed to return to a fully relaxed state when contractile tissue is not activated.

As discussed above, there may be a number of other causes of erectile dysfunction than venous leakage. Arterial insufficiency, for example, may lead to an inability to provide sufficient blood flow into the penis to cause or maintain an erection. Often, a subject may display symptoms of venous leakage and arterial insufficiency. In an embodiment, the stimulator is also arranged to stimulate a nerve or nerves affecting arterial blood supply, advantageously stimulating arterial blood supply, or to provide electrical stimulation that results in vasodilation of the arteries that provide blood to the penis.

In International Patent Application No. PCT/AU2006/00258, referred to above, a method and apparatus are disclosed for neurostimulation of nerves in a patient's anatomy in order to treat conditions such as urinary incontinence and fecal incontinence.

In an embodiment of the present invention, the stimulator is arranged to provide a signal or signals to

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stimulate one or more nerves in a patient's anatomy to treat other conditions. In an embodiment, the stimulator is arranged for stimulation of nerves to address urinary incontinence, in an embodiment urge incontinence (in which
5 there is an inappropriate urge to urinate). This condition is known to be treated by stimulation of the sensory nerves using a technique known as neuromodulation. In an embodiment of this invention, neuromodulation may be facilitated by stimulation of the Dorsal Penile Nerve
10 (DPN), which is a division of the Pudendal Nerve.

In an embodiment, the stimulator is an implantable stimulator arranged to be implanted within a patient.

In an embodiment, the apparatus has the advantage that it may be used where other treatments have failed.

15 In accordance with a second aspect, the present invention provides a device for facilitating an erection, the device including implanted contractile tissue positioned proximate or within the penile anatomy and arranged to be stimulated to contract to facilitate an
20 erection.

In an embodiment, the device is implanted in the form of ring about the penis, so that on constriction it constricts one or more veins and/or the cavernosal bodies.

25 In an embodiment the contractile tissue is implanted as a small wrap about one or more blood vessels e.g. the deep dorsal vein. Contraction of the tissue results in occlusion of the vein which facilitates erection.

In accordance with a third aspect, the present invention provides a controller for controlling an
30 stimulator which is arranged to stimulate contractile tissue positioned proximate or within the penile anatomy in order to facilitate an erection, the controller including means for providing a signal to the stimulator to vary the stimulation provided by the stimulator.

35 The controller may be arranged to provide a signal which causes the implantable stimulator to vary the stimulation (or remove stimulation) to allow the

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contractile tissue to contract or relax.

In an embodiment, the controller is arranged to generate a wireless signal to be received by a receiver associated with the stimulator.

5 In an embodiment, the stimulator is an implantable stimulator, that is, it is implantable within the patient.

In accordance with a fourth aspect, the present invention provides a programmer unit arranged to adjust parameters of the apparatus of the first aspect of the
10 present invention.

In accordance with a fifth aspect, the present invention provides a system for facilitating an erection, the system comprising an apparatus in accordance with the first aspect of the invention and a device in accordance
15 with the second aspect.

In an embodiment, the system also includes a controller in accordance with the third aspect of the invention.

In an embodiment, the system also includes a
20 programmer unit in accordance with the fourth aspect of the invention.

In accordance with a sixth aspect, the present invention includes a system for facilitating an erection, comprising an apparatus in accordance with the first
25 aspect of the present invention and a controller in accordance with the third aspect of the present invention.

In accordance with a seventh aspect, the present invention provides a system for facilitating an erection, comprising a apparatus in accordance with a first aspect
30 of the present invention and a programmer unit in accordance with the fourth aspect.

In accordance with an eighth aspect, the present invention provides a method of facilitating an erection, comprising the steps of stimulating contractile tissue
35 positioned proximate or in the penile anatomy of a patient in order to cause the contractile tissue to contract, by way of providing a stimulation signal to an electrode to

transmit the signal to the contractile tissue.

In an embodiment, the contractile tissue contracts and constricts in order to restrict venous blood flow and therefore maintain an erection.

5 In one embodiment, the method comprises the further step of providing a further signal, or absence of a signal, in order to enable the contractile tissue to relax.

10 In accordance with a ninth aspect, the present invention provides a method of facilitating an erection, comprising the steps of implanting into the patient a stimulator device arranged to provide stimulation signals to contractile tissue in order cause the tissue to contract to facilitate restriction of one or more blood
15 vessels and/or the cavernosal bodies in order to facilitate maintaining blood within the penis.

In one embodiment, the method comprises the further step of implanting the contractile tissue.

20 In accordance with a tenth aspect, the present invention provides a method of facilitating an erection, comprising the steps of implanting contractile tissue in a position proximate to or within the penile anatomy, the contractile tissue being arranged to be stimulated to contract about one or more blood vessels and/or the
25 cavernosal bodies in order to maintain blood within the penis in order to facilitate an erection.

In an embodiment, the erection is facilitated by being maintained because the blood is retained in the penis by the contracting action of the tissue. Blood flow
30 away from the penis is therefore restricted.

In accordance with an eleventh aspect, the present invention provides an apparatus for facilitating an erection in a patient, the apparatus including a stimulator arranged to provide a signal for stimulating a
35 nerve or nerves affecting the arterial blood supply to the penis.

In accordance with a twelfth aspect, the present

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invention provides a method of facilitating an erection in a patient, comprising the steps of stimulating a nerve or nerves to affect arterial blood supply to the penis.

5 In accordance with a thirteenth aspect, the present invention provides a method of treating a condition in a patient, comprising the steps of stimulating the Dorsal Penile Nerve in order to treat the condition.

10 In an embodiment, treatment is through neuromodulation, that is, using electrical stimulation in one neural pathway to modulate pre-existing activity in another.

In an embodiment, the condition is urinary incontinence, in an embodiment being urge incontinence.

15 In an embodiment, the condition is fecal incontinence.

Brief Description of the Drawings

20 Features and advantages of the present invention will become apparent from the following description of embodiments thereof, by way of example only, with reference to the accompanying drawings, in which:

25 Figure 1 is a cross section through the male pelvic anatomy schematically showing positioning of an apparatus and device in accordance with one embodiment of the present invention;

Figure 2 is a further section through the male pelvic anatomy showing positioning of an apparatus and device in accordance with a further embodiment of the present invention;

30 Figure 3 is a further section through the male pelvic anatomy showing positioning of an apparatus and device in accordance with a further embodiment of the present invention;

35 Figure 4 is a section through the male pelvic anatomy showing positioning of an apparatus and device in accordance with a further embodiment of the present invention;

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Figure 5 is a block diagram of components of an implantable stimulator in accordance with an embodiment of the present invention;

Figure 6 is a block diagram showing components of a system in accordance with an embodiment of the present invention; and

Figure 7 is a block diagram showing components of the system in accordance with an embodiment of the present invention;

Figure 8, 9 & 10 are exploded perspective, plan and side views, respectively, of an electrode arrangement for delivering stimulation signals in a system in accordance with an embodiment of the present invention;

Figures 11, 12, 13, 14 and 15 are perspective, plan, side section, detail views of a shroud component of the electrode arrangement of Figure 7;

Figures 16, 17, 18, 19, 20, are perspective, rear, plan section, side section and plan views of a cover component of the electrode arrangement of Figure 7

Figure 21 is a further cross section through the male pelvic anatomy schematically showing positioning of an apparatus in accordance with a third embodiment of the present invention; and

Figure 22 is a diagram illustrating interleaving signals of electrical stimulation in accordance with an embodiment of the present invention.

Detailed description of embodiments

Referring to Figure 1, a system in accordance with an embodiment of the present invention, for facilitating an erection, is shown. The system includes an apparatus comprising an implantable stimulator 1, and a device which comprises contractile tissue 2. The implantable stimulator 1, in this embodiment includes electronic circuitry which is arranged to provide an electrical

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signal for stimulating the contractile tissue 2. In this embodiment, an insulated conductor 3 conducts the signal or signals (one or more signals may be provided) to an electrode or electrodes implanted proximate or within the
5 contractile tissue 2.

The contractile tissue in this embodiment is formed into a band which is placed at the root of the penis 52 about the cavernosal bodies 50 and corpus spongiosum 51. In operation, when the contractile tissue 2 is stimulated,
10 it contracts about the cavernosal bodies 50 and corpus spongiosum 51. The cavernosal bodies carry important veins, in particular the dorsal vein of the penis 52. Contraction of the contractile tissue functions to constrict the veins in the corpus cavernosum. This in
15 turn functions to maintain blood in the penis and facilitate erection. In operation therefore, the stimulator may be activated to cause stimulation of the contractile tissue 2 during or before sexual stimulation to promote an erection, maintaining the erection once
20 sufficient blood has entered the penis 52. If the main blood vessels, such as the deep dorsal vein, do not retain blood in the penis, or there is a massive venous leakage condition, it is believed that the stimulation of the contractile tissue band 2 will assist in maintaining an
25 erection. Activation may occlude the main veins and/or occlude a tissue bed in order to retain the blood within the penis 52.

The implantable stimulator 1, in this embodiment, includes electronic circuitry in the form of a signal
30 generator which is mounted in a bio-compatible housing 4. A more detailed description of the stimulator of this embodiment will be given later on in this document.

A further embodiment is illustrated in Figure 2. In Figure 2 the same reference numerals have been used for
35 equivalent components to the Figure 1 embodiment. In the embodiment of figure 2, the contractile tissue band 2 is implanted within the body, behind the root of the penis

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around the crura 53. The operation of this embodiment is similar to that of the embodiment of Figure 1, merely the positioning of the contractile tissue being different.

Reference numeral 60 indicates in outline a further
5 alternative position for the contractile tissue band. It is implanted further into the body around the ends of the crura 53.

Note there may be a number of positions where the band may be placed.

10 Figure 3 illustrates yet a further embodiment. In this case there are two contractile tissue bands 2 and 2A. Band 2 is implanted in the same position as the band of the embodiment of Figure 1 and band 2A is implanted in the same position as the embodiment of Figure 2. A pair 3 and
15 3A of insulated conductors extend from the stimulator 4 to electrodes (not shown) implanted in the contractile tissue bands 2 and 2A. Both bands are therefore stimulated in use in order to facilitate erection.

The embodiment of Figure 3 may be most useful where
20 constriction along a substantial length of the penis is required in order to maintain an erection e.g. in severe cases of massive venous leakage.

Although two bands are illustrated in place in Figure 3, there may be more than two bands in place at various
25 positions, in alternative embodiments.

In a variation of this embodiment, the stimulator 4 may be arranged to selectively apply stimulation to one or other of the bands 2, 2A.

The dimensions of the implanted contractile tissue
30 band in the embodiments of Figures 1 to 3 may be varied. Relatively narrow width bands are shown in the Figures, but the bands may be wider than this if deemed necessary to treat the condition. The depth of the bands will also be selected in order for optimal effectiveness.

35 In the above embodiments a band is wrapped around a substantial part of the penis e.g. around the crural bodies. Although assisting in occluding venous flow, this

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may also have an effect on arterial blood flow to the penis. In an embodiment, stimulation may be applied to the contractile tissue after arterial blood flow has been allowed for some time. That is, if there is poor arterial
5 inflow, in this embodiment of the invention the timing of venous constriction can be manipulated to allow more filling time of the penis.

In other embodiments (see Figure 4 below) the contractile tissue may take the form of a wrap or wraps to
10 be wrapped around one or more blood vessels (veins) to specifically occlude particular blood vessel(s). In an embodiment, one or more blood vessels may be identified by a clinician as leaking more than the others and a contractile tissue wrap may be utilised to affect the
15 particular blood vessels which are identified as most prone to leakage of blood.

In Figure 4, a contractile tissue wrap 2C is implanted about the deep dorsal vein 54 of the penis 53. Stimulation applied to the wrap 2C by the stimulator 4
20 causes the wrap 2C to contract and occlude the deep dorsal vein. This therefore facilitates erection, particularly where there is a leakage problem with the dorsal vein. Two further alternative positions for the wrap are illustrated by reference numerals 2D and 2E.

25 Other blood vessels apart from the deep dorsal vein (although this is the major vein of the penis) may be treated in this way by implanting small contractile tissue wraps about the blood vessels to directly treat the leaking blood vessel itself. Other blood vessels that may
30 be provided with a contractile tissue wrap include the Superficial Dorsal Vein, the Crural Tip Veins and the Cavernous Veins in the penile hilum. Using contractile tissue bands around only the affected blood vessels avoids any potential problem with using a large contractile band
35 around the penis possibly occluding arterial blood flow to the penis.

Further, a combination of embodiments similar to

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Figures 1, 2 and 3 and the embodiment of Figure 4 could be utilised in severe cases, so that a band of contractile tissues encircling the cavernosal bodies and blood vessels is provided, and one or more (smaller) wraps about particular blood vessels such as the deep dorsal vein are also provided.

In the embodiments discussed above, the contractile tissue is smooth muscle tissue. The smooth muscle tissue may be obtained from elsewhere in the body, formed into a wrap or band and surgically implanted. Alternatively, the smooth muscle tissue may be grown from the smooth muscle stem cells and/or proliferative smooth muscle cells. Alternatively the smooth muscle tissue may be transplanted smooth muscle tissue augmented by smooth muscle stem cells and/or proliferative smooth muscle cells. The smooth muscle tissue in this embodiment is innervated (by nerves growing into it over a period of time following the implantation) and stimulation by the electrodes stimulates the nerves in the smooth muscle to cause the smooth muscle to contract.

International Patent Application No. PCT/2006/001301 referred to above, discloses augmentation of contractile tissue using proliferative smooth muscle cells or smooth muscle stem cells. Growth, maturation and stability of the tissue may be influenced by growth factors (trophic and/or neurotrophic factors) that are a component of the treatment.

The smooth muscle may be taken from the smooth muscle of the bladder. Alternatively, the muscle is venous smooth muscle, or coccygeus smooth muscle, terminal ileum transplanted as a segment devoid of mucosa and having its circulation intact. A further alternative is the dartos smooth muscle from the scrotum. A further alternative may be a portion of conveniently located vein. In each case, the long axes of the muscle cells are disposed substantially circumferentially about the wrap/band. Depending upon the muscle selected, the circulation may or

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may not be transplanted intact. If the circulation is not transplanted intact, new vessels will need to be regrown, or otherwise provided.

In an embodiment, smooth muscle may be taken as a free graft. In this case, the tissue is separated from its normal circulation and becomes vascularised by ingrowth of blood vessels at the site of implant.

The contractile tissue need not be smooth muscle, but could be other types of contractile tissue. For example, skeletal muscle tissue could be utilised. The tissue could also be synthetic contractile tissue.

The stimulator 1 is shown in more detail in Figure 5. In this embodiment, a signal generator that is arranged to provide the electrical signal for stimulation of the contractile tissue 2 is in the form of a control unit 9 and stimulus driver 10. The control unit 9 encodes the stimulus and provides a signal to the stimulus driver 10 which provides the stimulation signal at output 16. The output 16 outputs to conductor 3 and to one or more electrodes 40.

In this embodiment, the control unit 9 and stimulus driver 10 form, together with a demodulator 18, a processing unit for generating the stimulation signal(s) at output 16.

The demodulator 18 is arranged to demodulate a signal received by transceiver 15. An external control unit and external programmer unit (both to be described later) are able to communicate via the transceiver 15 with the processing unit 14 in order to control application of stimuli and/or vary the stimuli. In addition, as described in more detail later, the processing unit 14 may transmit, via control unit 9, demodulator 18 and transceiver 15, signals to a control unit or programmer unit. The transmitted signals may deliver telemetry information indicative of parameters of the stimulator, for the purposes of calibration and control.

The entire stimulator 1 (including components 14 and

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15), is enclosed in a housing 4 which includes a casing made from a bio-compatible material, such as titanium, silicone polymer or other inert materials. The frequency of the RF signal for transmission and reception by the transceiver 15 may depend on the material of the casing of the stimulator. The stimulator is fully implanted.

Figure 6 shows a system in accordance with an embodiment of the present invention. The system incorporates the implanted stimulator 1, with transceiver 15. The electrode(s) 40 is shown schematically together with cable 3.

The system also comprises an external controller 17 which includes a transmitter 11. The controller 17 is intended for operation by a patient with the stimulator implanted, for control of the stimulator 1.

The controller 17 includes means (such as a button, not shown) operable by the patient to selectively send signals to the implanted stimulator 1, for control of the stimulation signals being sent to the electrode(s) 40.

In this embodiment, no stimulation signals are sent until a signal is received from the controller 17. When the patient wishes to facilitate an erection (before or during sexual stimulation) they operate the controller 17 to send an "on" signal to the stimulator 1. In response to receiving the "on" signal, the controller unit 9 operates to turn the stimulating signal on, causing contractile tissue 2 to contract and facilitate and maintain an erection.

The controller 17 is also arranged to provide a further signal under patient control, once the patient no longer requires an erection, the further signal causing the stimulator 1 to stop providing the signal and to allow the contractile tissue to relax.

Where the contractile tissue is smooth muscle tissue, a stimulation signal 16 provided to contract the smooth muscle tissue 2 is selected so as to provide a substantially continuous tone in the smooth muscle. A

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charge-balanced biphasic pulse may be suitable for this. The signal has a substantially constant current less than or equal to 30 mA, and may be in the order of 15 mA. Stimulation pulse frequency provided to tissue 2 is in the
5 range of 0.25 Hz to 2.5 Hz and is preferably 2 Hz. Stimulation pulse width is in the range of 0.05 m/s to 0.02 m/s and is preferably 0.15 m/s. The stimulator is current regulated, and accordingly the stimulation voltage will vary with the resistance of the muscle tissue between
10 the electrodes. Typical values for the voltage are between 0.2 and 7 volts.

In a further embodiment, the stimulation signal may be a generally rectangular and symmetrically biphasic pulse. The signal has a substantially constant current
15 less than or equal to 50 mA, 15 mA, 10 mA, or 5 mA, and in some preferred embodiments may be in the order of 4 mA, 8 mA, 12 mA, or 15 mA.

Stimulation pulse frequency provided to sphincter 1 may be in the range of 0.1 Hz to 5 Hz, 0.2 Hz to 4.0 Hz.
20 0.25 Hz to 3.0 Hz, 1 Hz to 3.0 Hz, 1.5 Hz to 3 Hz, 1.75 Hz to 2.5 Hz, or a 0.25 Hz to 2.25 Hz, and in one embodiment, is 1 Hz, 2 Hz, 2.5 Hz or 3 Hz. Stimulation phase width of each phase may be in the range of 0.05 ms to 2.0 ms, 0.1ms to 1.5 ms, 0.2 ms to 1 ms, 0.25 ms to 0.75 ms, and in one
25 embodiment is 0.2 ms, 0.4 ms, 0.5 ms or 1 ms. The stimulator is current regulated, and accordingly the stimulation voltage will vary with the resistance of the muscle tissue between the electrodes.

Typical values for the voltage may be between 0.1 and
30 15 Volts, 0.2 and 12 Volts, 0.5 and 12 Volts, 0.5 and 10 Volts, or 0.5 and 7.5 Volts. In one embodiment, the voltage is 2.5 Volts, 5 Volts, 7.5 Volts or 10 Volts. Either a current source (voltage limited) or a voltage source (current limited) stimulator may be used.

35 The controller unit may not only be a simple "on-off"

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device. It may enable the user to apply some control over the strength of the signal to be applied to the contractile tissue 2. This may enable the user to vary the extent of contraction of the tissue.

5 In an embodiment, the controller unit includes a controller enabling a user to vary the stimulation level for comfort and maintenance of an erection. For example, the controller may be used by the patient to increase stimulation if erection is not being maintained.

10 In one embodiment, the stimulator may default to the last stimulation level used to maintain the erection when it was last turned on.

In one embodiment, the stimulator may operate to slowly ramp up the stimulation so that there is less awareness of unwanted side effects by the patient. In another embodiment, this may not be required.

Figure 7 shows a system in accordance with an embodiment of the present invention, including a programmer unit 13 which may be utilised by a physician to set and adjust parameters of the implanted stimulator 1. The programmer unit 13 is arranged to communicate with the stimulator via transceiver 11, and may include a computing device. The control unit 9 is also arranged to transmit stimulator telemetry information indicative of one or more of the parameters of the stimulator 1, for detection by the programmer 13 via transceiver 11. The programmer unit 13 can therefore determine parameters of the stimulator from telemetry information and can adjust the parameters by transmitting control signals to the stimulator 1. The signals from the programmer may be able to selectively vary the output current, shape, frequency and/or pulse width of the stimulation signal(s).

In operation, a physician adjusts parameters of the stimulation signal(s). The physician will note feedback from the patient as to the effect of the stimulus, and may subsequently re-adjust the parameters until the stimulation is optimum. For example, patient perceived

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feedback may be used to set the maximum stimulation threshold of a smooth muscle sphincter.

In the above-described embodiments, signals between the controller or programmer and the stimulator are RF signals. Other types of transmission media other than RF may be used. For example, microwave signals may be used for transmission, optical signals may be used, and in another embodiment magnetic transmission may be used.

Magnetic transmission may be used for the controller 17 to cause the stimulator to stop producing stimulation signals. In this embodiment, the controller 17 may be a simple magnet which, when passed over a magnetic receiver of the stimulator 1, results in the stimulator commencing to provide stimulation signals, and when passed over the stimulator 1 again, results in the stimulator ceasing to provide stimulation signals.

Other means than magnetic transmission may be utilised.

In the above embodiment, the implantable stimulator 1 is shown implanted within the patient in the abdomen. It may be implanted in any part of the patient that is convenient.

In the above embodiment, the stimulator is totally implantable. It is possible that the stimulator may be partly implantable and partly exterior. That is a signal generator could be placed exterior to cause an implanted conductor to conduct signals to the contractile tissue. The implanted conductor may include an electrode and an apparatus arranged to receive the stimulation signals from the external stimulator. The stimulator may be of any other configuration.

In the above embodiments, there may be one or more electrodes implanted in the contractile tissue at predetermined location(s). Types of electrode configurations that may be employed include bipolar electrodes, tripolar electrodes, cuff-type electrodes and other electrode types. In one embodiment, a "clothes peg"

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type electrode may be utilised, such as disclosed in applicants co-pending international patent application number PCT/AU2005/001698, referred to above. This type of electrode includes a pair of electrode elements extending
5 parallel to each other and positionable either side of a contractile tissue band to provide stimulation to the portion of the band between the electrode elements.

Electrodes of a clothes peg type which may be used to stimulate the contractile tissue will now be described.

10 The electrode comprises a number of components. These include an electrode cover 100 (shown in most detail in Figures 15 through 20).

The components also include an electrode shroud (shown in best detail in Figures 11 through 14) and also
15 an electrode lead 102 (shown in Figures 8, 9 & 10, together with the other components of the electrode arrangement).

In this embodiment first and second electrode elements are formed by the electrode cover 100, which
20 includes insulating elements 103,104 extending from a base 105. The insulating extending elements 103,104 are formed with a slot 106,107, respectively, extending substantially along the length of the extending elements 103,104. When the electrode arrangement is assembled, platinum foil
25 electrodes 108,109 (Figure 8) are placed on the outer surfaces of the elements of the elements 103,104 so that they are insulated from the gap 110 formed between the elements 103,104 apart from the slots 106,107, which expose portions of the conductive plates 108,109 to the
30 gap 110 (and, in use, to any tissue seated within the gap).

When assembled, the electrode cover 100 and platinum electrode foils 108,109 seat within the electrode shroud 101 as best shown in Figures 11, 12, 13 & 14. Figure 14

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in particular shown in cross-section where the electrode cover seats.

Electrode shroud 1 is formed from silicone. In order to provide reinforcement, PET mesh covers 111,112 are provided to fit to upper 113 and lower 114 extending portions of the shroud 101. Suture holes 115,116 are provided in the covers 111,112 and also in the elements 113,114 of the shroud 101. Note that the reinforcement can be provided by other means and is not limited to PET mesh. Further, the electrode shroud need not be in silicone but could be of other bio-compatible material and may not require re-inforcement. Further, note that other means for affixing to the tissue may be provided other than suture holes or instead of suture holes.

The electrode lead 102 is a multi-component arrangement which includes an outer insulating cover 120, a tine collar 121 including tines 122 for retaining the lead in position within a patient. It also includes a sutured collar 123 including suture holes 124 for suturing to patient tissue to also facilitate retaining the lead 102 in position. There is also bifurcation moulding 125 which enables the lead to split into two parts 126,127 which may contain separate conductors, and connectors 128,129 which may be arranged to contact to a stimulation device.

In the above embodiments, the electrode arrangement includes a pair of electrode elements which extend away from a base which joins them together at their proximal ends. In a further embodiment, a single electrode element which is not joined at any base is provided. This single electrode element may be used to provide stimulation to contractile tissue on its own, or may be used together

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with one or more similar electrode elements to provide stimulation.

In the above described embodiments, each electrode element is provided with a single electrode. The single
5 electrode is an elongate electrode extending substantially the majority of the length of the electrode element.

One advantage of having thin electrodes bounded by insulating material on either side is that the arrangement operates to confine the electric field produced by the
10 electrode to the tissue immediately adjacent the electrode. This reduces or prevents stimulation of tissue that it is not desirable to stimulate eg. tissue external to a contractile tissue sphincter being controlled.

In operation, the electrodes 108, 109 and extending
15 elements 103, 104 are positioned either side of the smooth muscle implant to enable signals to be transmitted to the implant for operation.

The electrode arrangement allows application of an electric field between the opposing electrode elements to
20 stimulate the tissue between them. The electric field in one embodiment is confined so that stimulation is to a *band* of tissue between the electrodes.

In one embodiment, innervation runs within the implant 2 perpendicular to the band of tissue being
25 stimulated.

The elements in the electrode extend over the tissue in a manner analogous to that of a clothes peg.

Other electrode patterns than a single line electrode on the surfaces of the elements may be utilised.

30 Figure 8A discloses one alternate electrode pattern.

As discussed above, in an embodiment, the stimulator implant is preferably sealed and encased in a biologically inert material such as a biocompatible silicone material.

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Metallic electrodes and leads may be of platinum-iridium alloy. The connecting wires are, in one embodiment, insulated with a silicon coating.

In a further embodiment of the present invention, a
5 stimulator is also arranged to apply stimulation to a nerve or nerves as to affect arterial blood supply to the penis. This is advantageous where the patient also has a problem with arterial blood flow to the penis (as well as a problem with venous leakage).

10 Figure 21 illustrates a further embodiment of the invention. A further electrode lead 100 is illustrated in this embodiment, providing a signal to an electrode or electrodes 101 for stimulation of nerves associated with arterial function. Note the position of the electrode 101
15 is for the purposes of illustration only, and is not accurate. An electrode or electrodes may be placed in position which can affect arterial blood flow by a nervous stimulation, and the position will be selected by the clinician.

20 In this embodiment, the signal generator 4 also provides stimulation signals to the electrode(s) 101 for stimulation of arterial blood flow. Stimulation may be provided at the same time or slightly in advance of stimulation to the contractile tissue 2, in order to
25 facilitate erection. The time, frequency and extent of stimulation to electrodes 101 will be determined by the clinician and will depend on the condition of the patient. In this embodiment, the control unit and programmer unit may include circuitry for affecting control of the
30 signal 100 for stimulating the electrode(s) 101.

In a further aspect of the invention, stimulation of the nerve or nerves to affect arterial blood flow may be carried out without stimulation of any contractile tissue

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to affect venous blood flow. That is, the arterial condition may be treated separately. In this embodiment, there may be no contractile tissue and no electrode or stimulation to any contractile tissue.

5 In accordance with a further embodiment, the stimulator 4 may also produce signals to stimulate nerves to affect other conditions that the patient may have. Such stimulation may be termed neuromodulation in which activity in one neural pathway modulates the pre-existing
10 activity in another.

For example, the patient may also suffer from urinary incontinence, and a further stimulation signal may be provided by the stimulator 4 to stimulate one or more convenient sensory nerves to assist with the management of
15 this urinary incontinence condition. This may particularly affect urge incontinence (although the embodiment is not limited to treating urge incontinence). The Dorsal Penile Nerve is a branch of the pudendal nerve, that originates from the sacral outflow from the spinal
20 chord. Low levels of stimulation to the DPN may illicit neuromodulation effects to overcome an inappropriate urge to urinate. In an embodiment, stimulation to the contractile tissue may also deliver stimulation to the Dorsal Penile Nerve.

25 Neuromodulation is not limited to the Dorsal Penile Nerve, however, and other nerves in the anatomy may be stimulated. Figure 21 illustrates an example an electrode lead 102 from a stimulator 4 travelling to an electrode 103 for stimulation of nerves within the
30 patient's pelvic anatomy.

Neuromodulation may also be under patient control via the controller and clinician control via the programmer unit.

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In operation, neuromodulation may be carried out by the Dorsal Penile Nerve which is convenient to the site of placement of the smooth muscle wrap, or, alternatively, any other nerve that is appropriate to treat urge
5 incontinence. A neuromodulating effect may also occur at the same time as the signals being provided to the contractile tissue to maintain an erection. Alternatively neuromodulation may be turned off when the signal is provided to the contractile tissue.

10 A single electrical signal of a predetermined pattern may be used to stimulate the contractile tissue and the one or more nerves. In other embodiments, however, separate signals may be provided for neuromodulation and stimulation of the contractile tissue.

15 The step of applying neuromodulation to stimulate the one or more nerves may comprise initially applying electrical signals at relatively low level and increasing to the required level. This "ramping up" may reduce annoying perception of the stimulation by the patient.
20 Otherwise they may perceive this stimulation as unpleasant tingling, for example.

The stimulation of the contractile tissue may be by relatively low frequency signals for stimulation of the contractile tissue, and stimulation of one or more nerves
25 for neuromodulation by a relatively high frequency signal. The low frequency signal may be from 1Hz to 5Hz and the relatively high frequency signal 5Hz to 200Hz.

A relatively low intensity signal may be utilised for neuromodulation and a relatively high intensity signal for
30 stimulation of the contractile tissue.

A plurality of electrodes placed in various positions may be used to provide the neurostimulation. Each electrode may deliver a distinct electrical signal to a

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plurality of different sites in order to effect the required nerve stimulation. As discussed above, the same signal that is used to stimulate the contractile tissue may be used to provide the neurostimulation. This is unlikely, however, as different properties may generally be required of the signals. In an embodiment, therefore, either separate signals are provided (separate channels) or the signals may be interleaved. In either case the stimulation parameters are distinct for the different purposes of (i) stimulating the contractile tissue and (ii) stimulating one or more nerves e.g. Dorsal Penile Nerve.

Figure 13 shows a diagram of an example of an interleaved-type signal. The signal 600 for stimulation of the one or more nerves has a relatively small amplitude and a higher frequency. The signal 601 for stimulating the contractile tissue, has a relatively large amplitude and low frequency.

A relatively high frequency signal may be used to provide the stimulation for the nerves and a relatively low frequency signal to stimulate the tissue. The relatively high frequency signal may be greater than 5 Hz, preferably greater than 8 Hz and even more preferably 10 Hz or greater. In one embodiment, the high frequency signal is up to 100 Hz.

The low frequency signal, for stimulation of the tissue, will usually be less than 5 Hz and may be 2 Hz or less.

A relatively low intensity signal may be used to stimulate the nerves and a relatively high intensity signal for the tissue. The low intensity signal in this embodiment is a pulse signal. The pulse signal may have

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300 us or less pulse width and a 3 mA or less current, and in this embodiment 200 us or less and 1 mA current.

The high intensity tissue stimulating signal may have pulse width greater than 300 us and a current of greater than 3 mA, and in this embodiment is 400 us or more and the current is 4 mA.

The duty cycle for the nerve stimulating signal may vary. As discussed above in this embodiment it is 5 minutes on and 5 minutes off but in other embodiments may be 5 minutes or more on and 15 minutes or more off, 5 minutes or less off and 5 minutes or less on. Duty cycle and other signal characteristics may be adjusted to provide the most effective stimulation. In some embodiments, the duty cycle may be in terms of seconds (e.g. less than 10 seconds on and less than 30 seconds off).

With the nerve stimulation signal, it is possible that the patient may experience some discomfort (e.g. 'tingling') on application of the signal. Where the signal is applied in accordance with a duty cycle, this tingling may be experienced in rhythm with the duty cycle. In one embodiment, the afferent nerve stimulating signal may be "ramped up" from a relatively low intensity to the required intensity each time it is applied. This may reduce unwanted awareness of the stimulation or patient discomfort.

The electrodes employed may incorporate an electrically conductive surface that is in contact with the contractile tissue, which also activates afferent nerve fibres. In another embodiment, the electrode for the tissue may include one or more additional electrically conductive surfaces that are on the outer surface of the electrode, to stimulate nerve endings in the surrounding

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anatomy. In yet a further embodiment, the electrode may be entirely separate to the electrode used to stimulate the tissue, but placed conveniently in the adjacent anatomy to facilitate delivery of electrical stimulation to neurostimulate the bladder reflexes.

Neuromodulation may be used to treat other conditions in urge incontinence. It may be used to treat fecal incontinence, for example.

The interleaved signals shown in Figure 22 may not operate at the same time. For example, signal 601 may only be required to operate when erection maintenance is required.

Embodiments of the present invention may be utilised not only to treat conditions of erectile dysfunction brought about by venous leakage or massive venous leakage. They may assist in treatment for psychological conditions, for example, where it is difficult to maintain an erection because of a psychological difficulty. It is envisaged that embodiments may even be utilised where there is no particular erectile dysfunction condition. For example, to enhance sexual performance e.g. by maintaining erections for longer periods of time.

Positioning of the contractile tissue bands of the embodiments of Figures 1 to 3 may also be governed by aesthetic requirements. Positioning of a band of contractile tissue about the base of the penis, for example, may effectively increase girth of the penis.

In the claims which follow and in the preceding description of the invention, except where the context requires otherwise due to express language or necessary implication, the word "comprise" or variations such as "comprises" or "comprising" is used in an inclusive sense, i.e. to specify the presence of the stated features but not to preclude the presence or addition of further features in various embodiments of the invention.

It will be appreciated by persons skilled in the art

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that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments
5 are, therefore, to be considered in all respects as illustrative and not restrictive.

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THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. An apparatus for facilitating an erection in a patient, the apparatus including a stimulator arranged to
5 provide a signal for stimulation of contractile tissue, in order to facilitate an erection.
2. An apparatus in accordance with Claim 1, wherein the contractile tissue is positioned proximate to the penis and on contraction is arranged to constrict one or more
10 blood vessels and/or the cavernosal bodies.
3. An apparatus in accordance Claim 2, wherein the contractile tissue is implanted in the form of a band about the root of the penis.
4. An apparatus in accordance with Claim 2 or Claim 3,
15 wherein the contractile tissue is implanted as a band within the body about the left and right crura.
5. An apparatus in accordance with any one of the preceding claims, the contractile tissue being placed about one or more blood vessels.
- 20 6. An apparatus in accordance with Claim 5, wherein the contractile tissue is implanted as a wrap about the deep dorsal vein.
7. An apparatus in accordance with any one of the preceding claims, wherein the contractile tissue is smooth
25 muscle tissue.
8. An apparatus in accordance with any one of the preceding claims, wherein the contractile tissue is skeletal muscle.
9. An apparatus in accordance with any one of the
30 preceding claims, wherein the signal is in the form of a pulse signal, arranged to maintain tone in the contractile tissue.
10. An apparatus in accordance with any one of the preceding claims, the stimulator being arranged to provide
35 a different stimulation signal or no stimulation signal in order to allow the contractile tissue to relax.
11. An apparatus in accordance with any one of the

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preceding claims, the stimulator being further arranged to stimulate a nerve or nerves affecting arterial blood supply to the penis.

12. An apparatus in accordance with any one of the
5 preceding claims, the stimulator being arranged to provide a signal to stimulate one or more nerves in the patient's anatomy to treat another condition.

13. An apparatus in accordance with claim 12, wherein the condition is urinary incontinence.

10 14. An apparatus in accordance with claim 13, wherein the condition is urge incontinence.

15. An apparatus in accordance with claim 12, wherein the condition is fecal incontinence.

15 16. An apparatus in accordance with any one of claims 12 to 15, wherein the one or more nerves comprises the Dorsal Penile Nerve.

17. A device for facilitating an erection, the device including implanted contractile tissue positioned proximate or within the penile anatomy and arranged to be
20 stimulated to contract to facilitate an erection.

18. A device in accordance with Claim 17, wherein the contractile tissue is positioned proximate to the penis and on contraction is arranged to constrict one or more blood vessels and/or the cavernosal bodies.

25 19. A device in accordance Claim 18, wherein the contractile tissue is implanted in the form of a band about the root of the penis.

20. A device in accordance with Claim 18 or Claim 19, wherein the contractile tissue is implanted as a band
30 within the body about the left and right crura.

21. A device in accordance with any one of Claims 17 to 14, the contractile tissue being placed about one or more blood vessels.

22. A device in accordance with Claim 21, wherein the
35 contractile tissue is implanted as a wrap about the deep dorsal vein.

23. A device in accordance with any one Claims 17 to 22

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wherein the contractile tissue is smooth muscle tissue.

24. A device in accordance with any one Claims 17 to 23, wherein the contractile tissue is skeletal muscle.

25. A controller for controlling a stimulator which is
5 arranged to stimulate contractile tissue positioned proximate or within the penile anatomy in order to facilitate an erection, the controller including means for providing a signal to the stimulator to vary the stimulation provided by the stimulator.

10 26. A controller in accordance with Claim 25, the controller being arranged to provide a signal which causes the stimulator to vary the stimulation (or remove the stimulation) to allow the contractile tissue to relax.

27. A controller in accordance with Claim 25 or Claim 26,
15 the controller being arranged to provide a signal which causes the signal strength generated by the implantable stimulator to vary, to vary the magnitude of stimulation.

28. A programmer unit arranged to adjust parameters of the apparatus of any one of Claims 1 to 16.

20 29. A system for facilitating an erection, the system comprising an apparatus in accordance with any one of Claims 1 to 16 and a device in accordance with any one of Claims 17 to 24.

30. A system in accordance with Claim 29, further
25 including a controller in accordance with any one of Claims 25 to 27.

31. A system in accordance with Claim 29 or Claim 30, further including a programmer unit in accordance with Claim 28.

30 32. A system for facilitating an erection, including an apparatus in accordance with any one of Claims 1 to 16, and a controller in accordance with any one of Claims 25 to 27.

33. A system for facilitating an erection, including an
35 apparatus in accordance with any one of Claims 1 to 16, and a programmer unit in accordance with Claim 28.

34. A method of facilitating an erection, comprising the

steps of stimulating contractile tissue positioned proximate or in the penile anatomy of a patient in order to cause the contractile tissue to contract, by way of providing a stimulation signal to an electrode arranged to transmit the signal to the contractile tissue.

35. A method in accordance with Claim 34, comprising the further step of providing a further signal, or absence of a signal, in order to enable the contractile tissue to relax.

36. A method in accordance with claim 34 or claim 35, comprising the further step of providing a signal for stimulation of a nerve or nerves affecting arterial blood supply to the penis.

37. A method in accordance with claim 34, 35 or 36, further comprising the step of providing a signal to stimulate one or more nerves in a patient's anatomy to treat another condition.

38. A method in accordance with claim 37, wherein the condition is urinary incontinence.

39. A method in accordance with claim 38, wherein the condition is urge incontinence.

40. A method in accordance with claim 37, wherein the condition is fecal incontinence.

41. A method in accordance with any one of claims 37 to 40, wherein the one or more nerves comprises the Dorsal Penile Nerve.

42. A method of facilitating an erection, comprising the steps of implanting into the patient a stimulator device arranged to provide stimulation signals to contractile tissue in order cause the tissue to contract to facilitate restriction of one or more blood vessels and/or the cavernosal bodies in order to facilitate maintaining blood within the penis.

43. A method in accordance with Claim 42, comprising the further step of implanting the contractile tissue.

44. A method in accordance with Claim 43, wherein contractile tissue is implanted as a band about the penis.

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45. A method in accordance with Claim 44, wherein the band is implanted about the root of the penis.

46. A method in accordance with Claim 44 or Claim 45, wherein the band is implanted within the body about the
5 crural bodies.

47. A method in accordance with any one of Claims 43 to 46, wherein the contractile tissue is implanted in the form of a wrap about a blood vessel.

48. A method in accordance with any one Claims 42 to 47,
10 wherein the contractile tissue is smooth muscle tissue.

49. A method in accordance with any one of Claims 42 to 49, wherein the contractile tissue is skeletal muscle.

50. A method of facilitating erection, comprising the steps of implanting contractile tissue in a position
15 proximate to or within the penile anatomy, the contractile tissue being arranged to be stimulated to contract about one or more blood vessels and/or the cavernosal bodies in order to maintain blood within the penis in order to facilitate an erection.

20 51. An apparatus for facilitating an erection in a patient, the apparatus including a stimulator arranged to provide a signal for stimulating the nerve or nerves affecting arterial blood supply to the penis.

52. A method of facilitating an erection in a patient,
25 comprising the steps of stimulating a nerve or nerves to affect arterial blood supply to the penis.

53. A method of treating a condition in a patient, comprising the steps of stimulating the Dorsal Penile Nerve in order to treat the condition.

30 54. A method in accordance with claim 53, wherein the condition is urinary incontinence.

55. A method in accordance with claim 53, wherein the condition is fecal incontinence.

56. A method in accordance with claim 54, wherein the
35 condition is urge incontinence.

57. An apparatus for treating a condition in a patient, the apparatus comprising the stimulator being arranged to

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provide stimulation to the Dorsal Penile Nerve in order to treat the condition.

58. An apparatus in accordance with claim 57, wherein the condition is urinary incontinence.

5 59. An apparatus in accordance with claim 58, wherein the condition is urge incontinence.

60. An apparatus in accordance with claim 57, wherein the condition is fecal incontinence.

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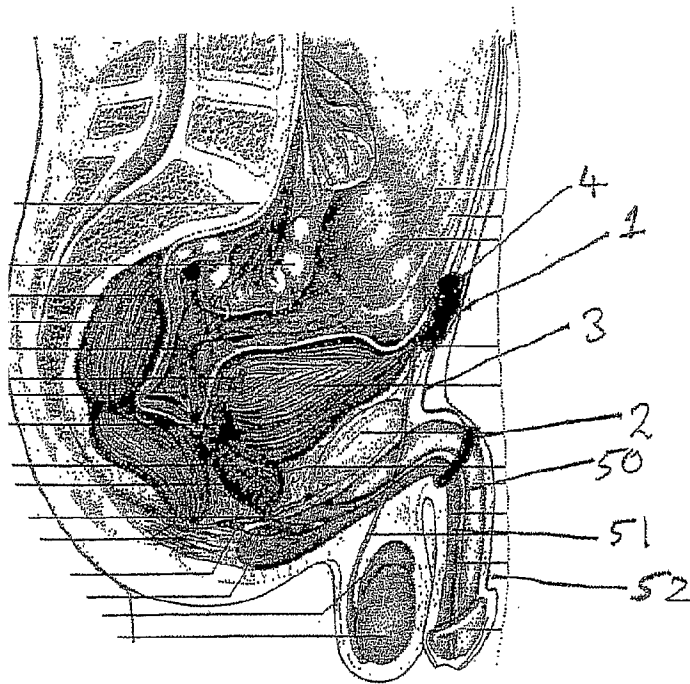


FIGURE 1

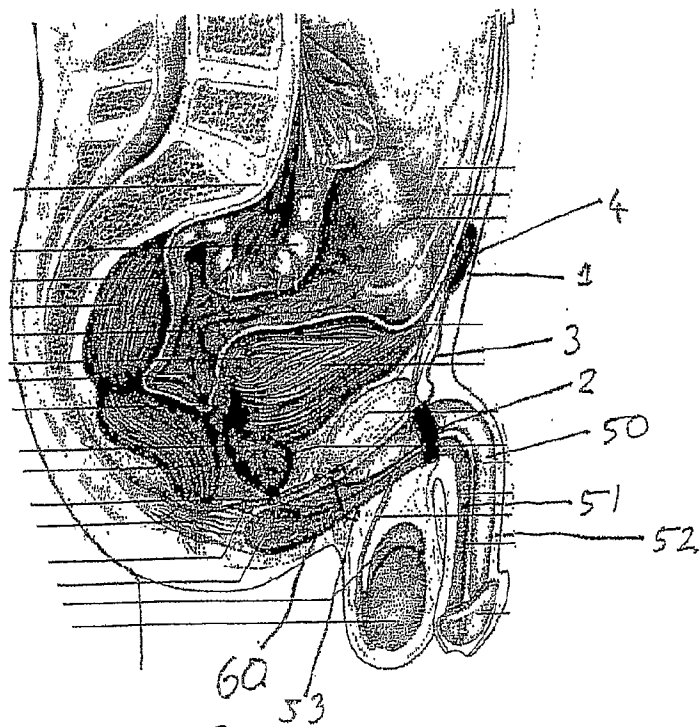


FIGURE 2

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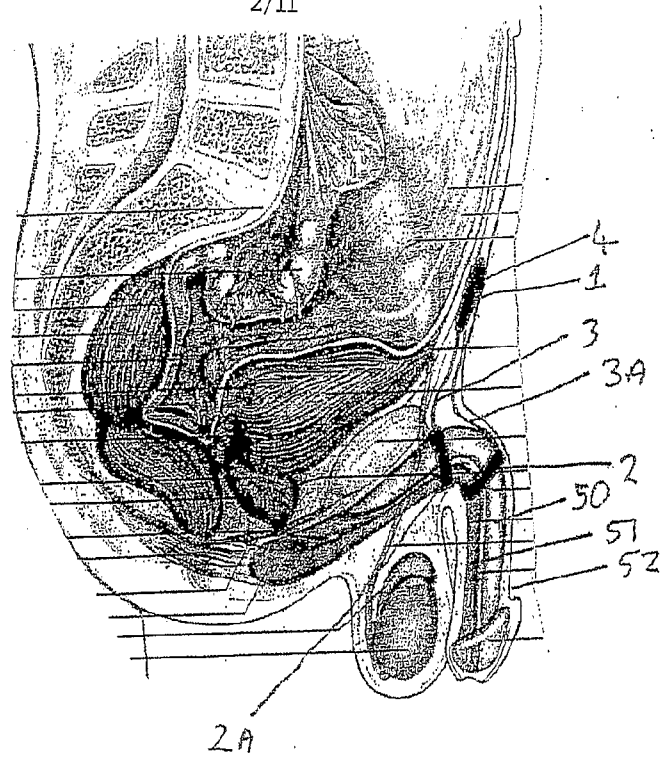


FIGURE 3.

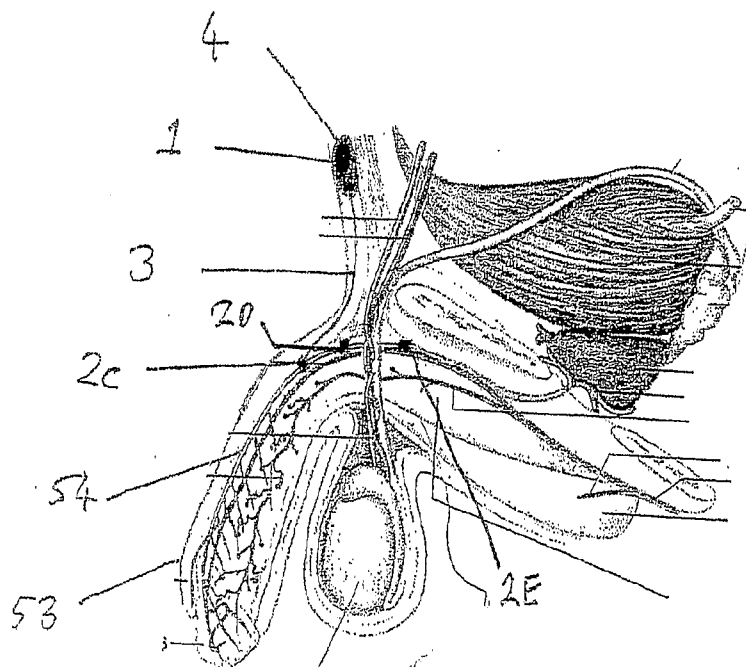


FIGURE 4.

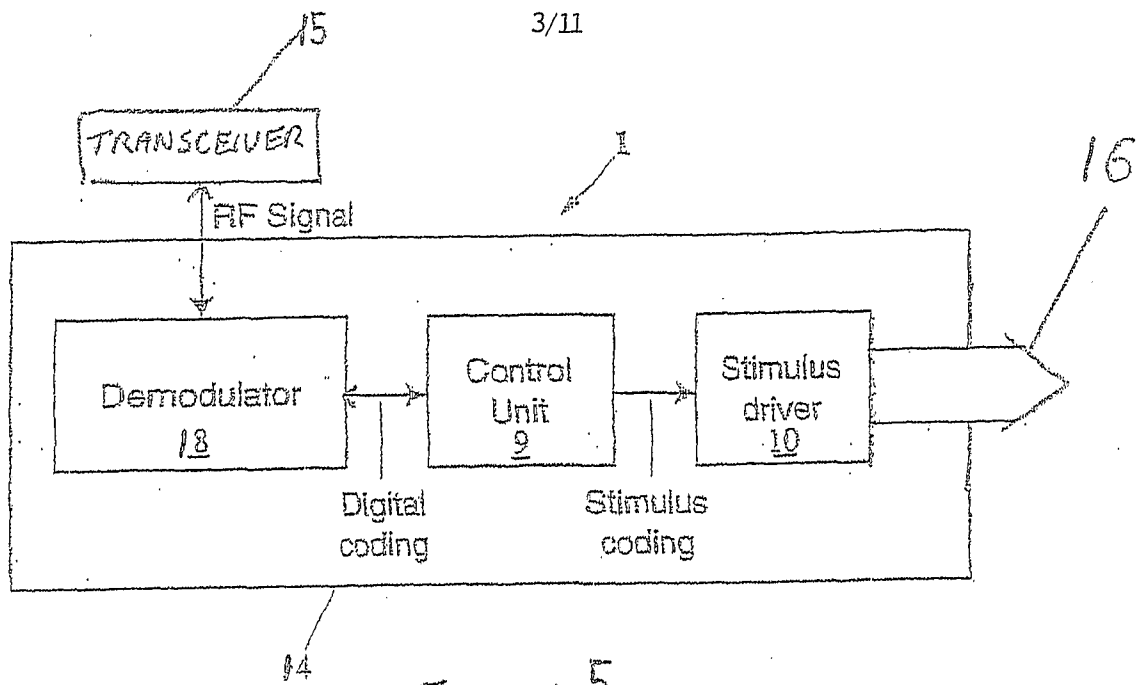


FIGURE 5

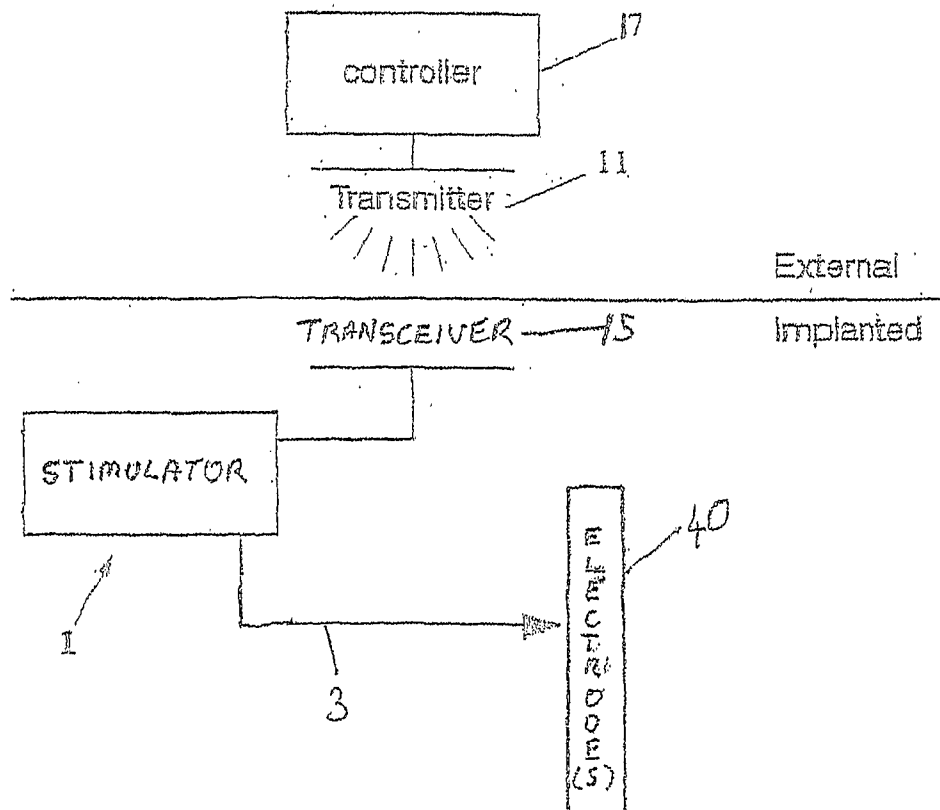


FIGURE 6

4/11

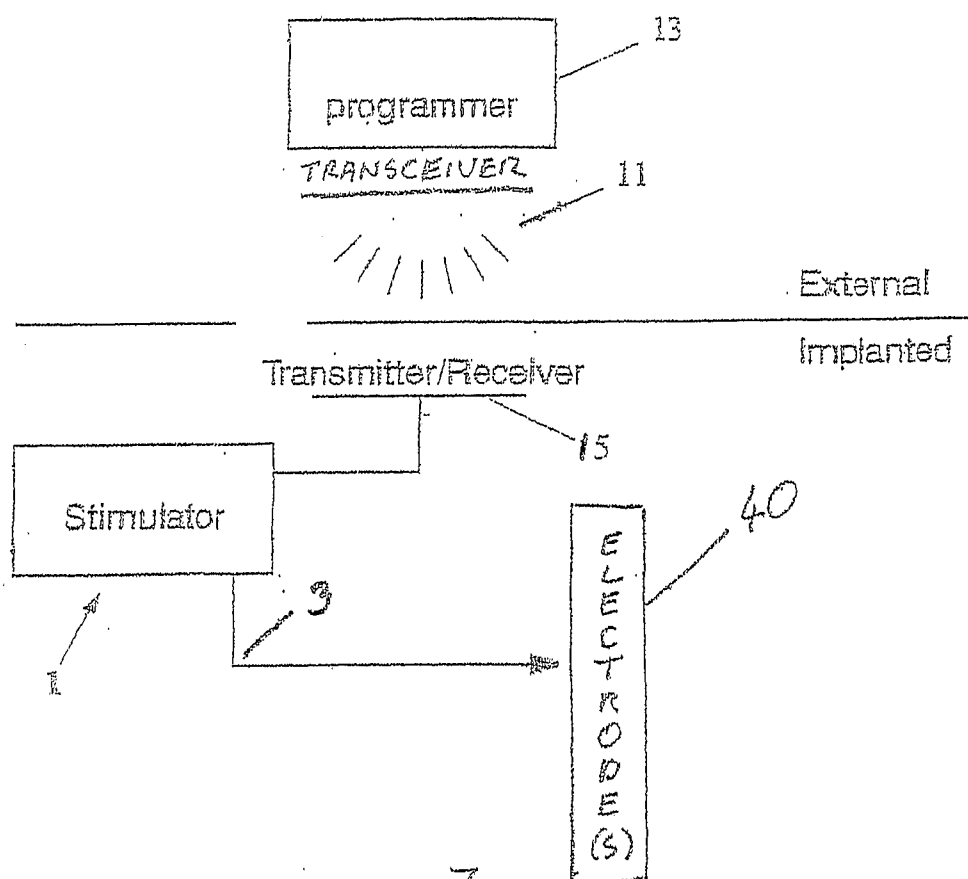


FIGURE 7

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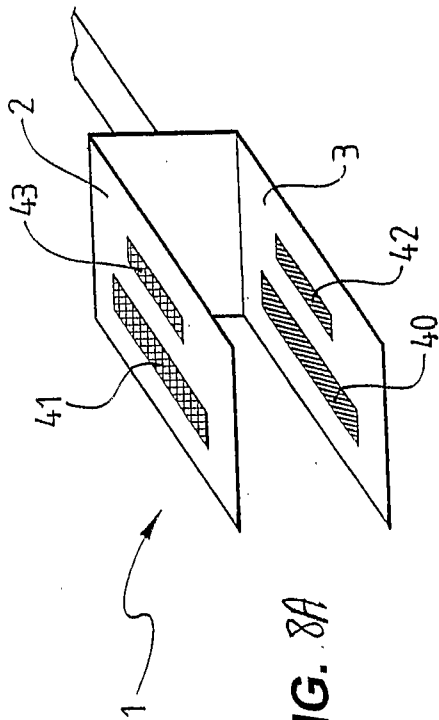


FIG. 8A

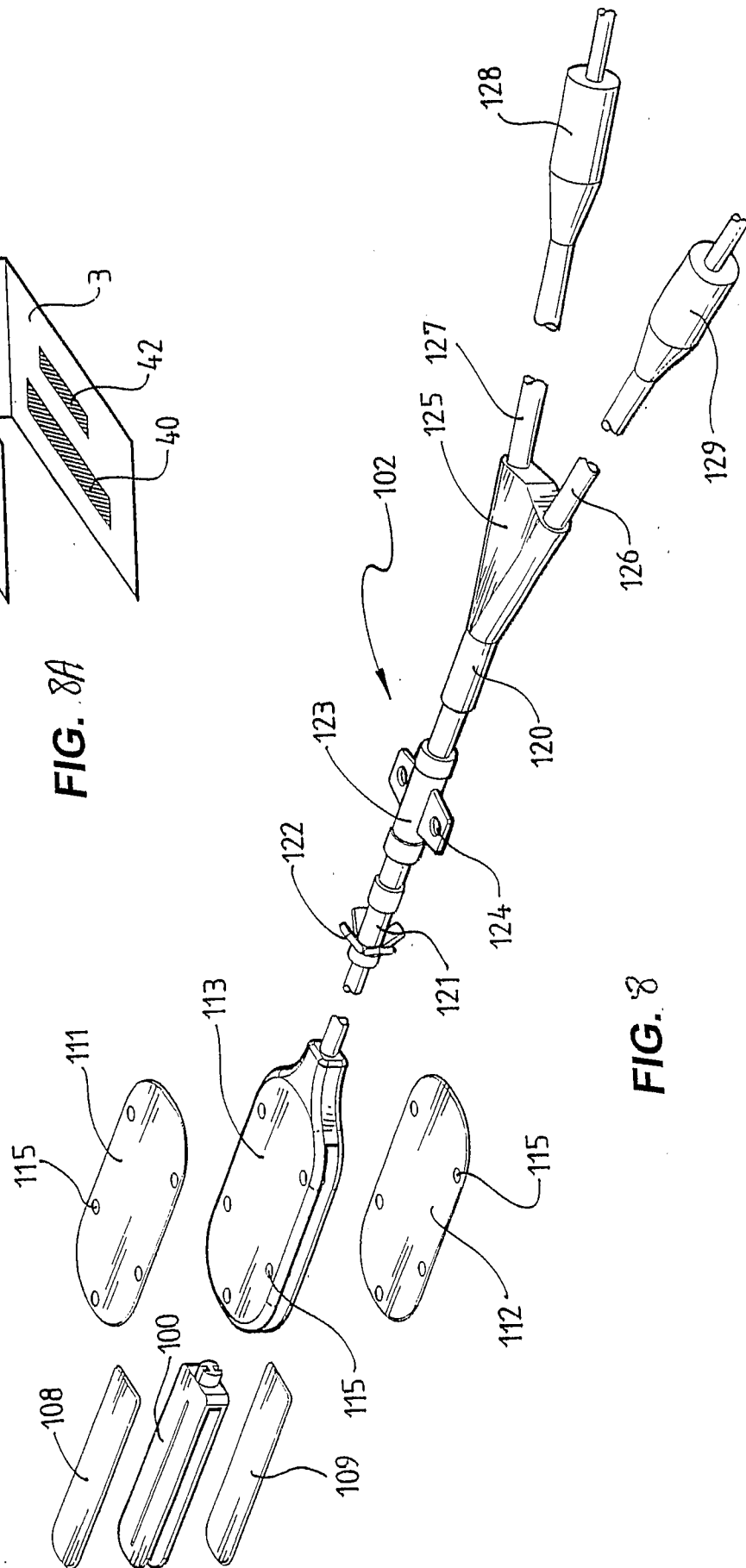
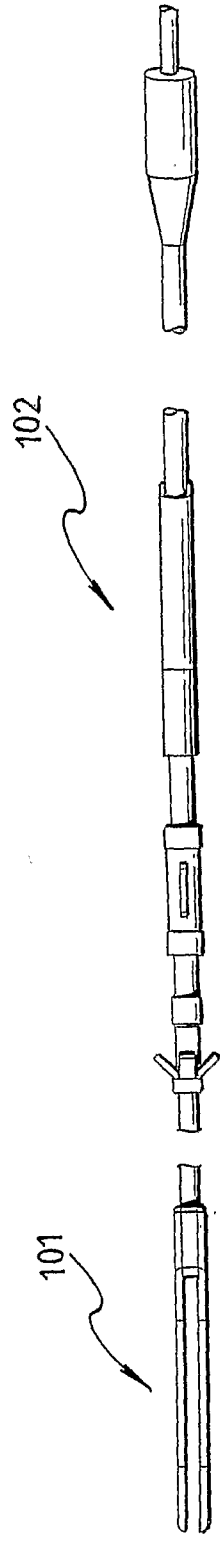
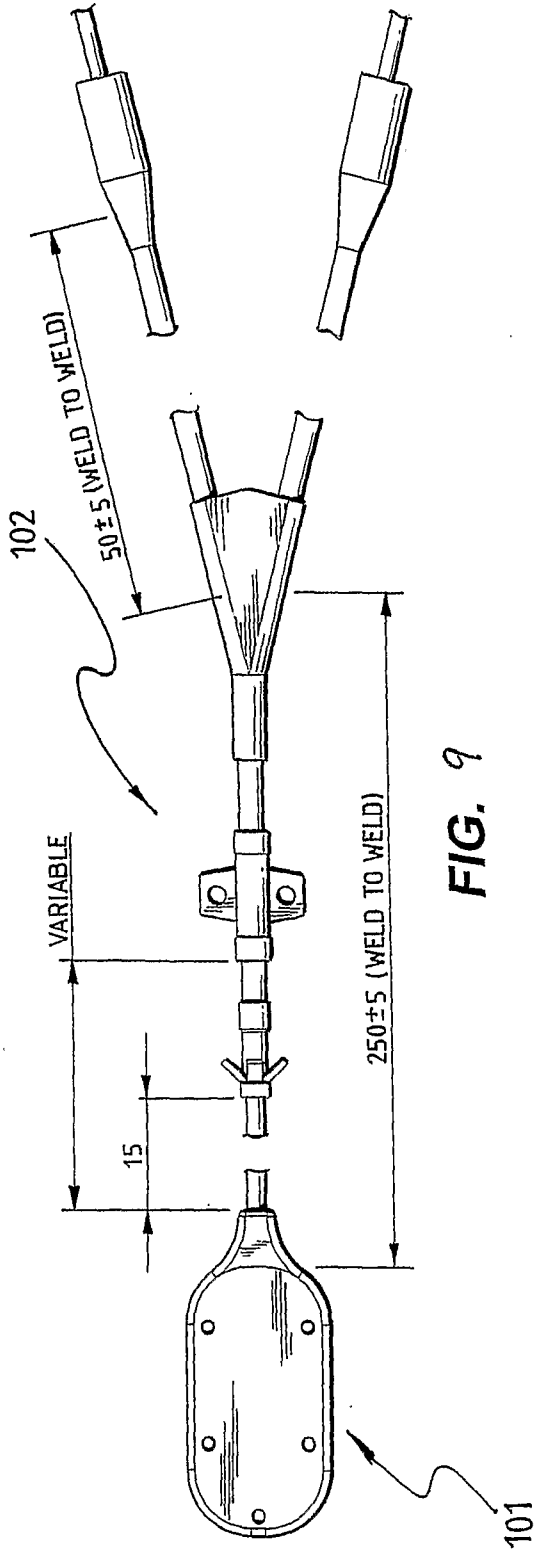


FIG. 8



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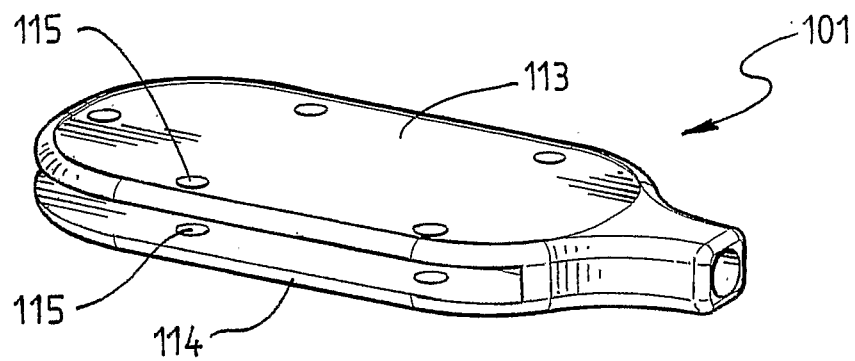


FIG. 11

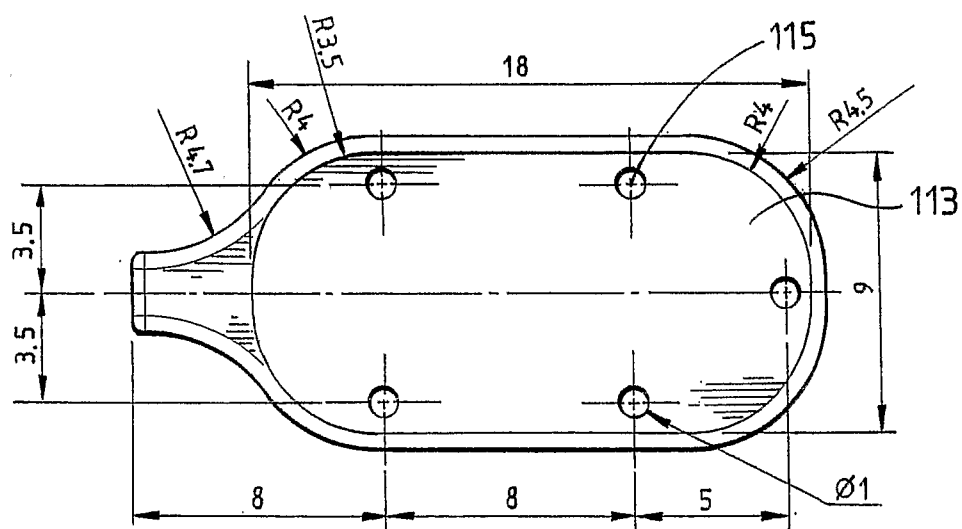


FIG. 12

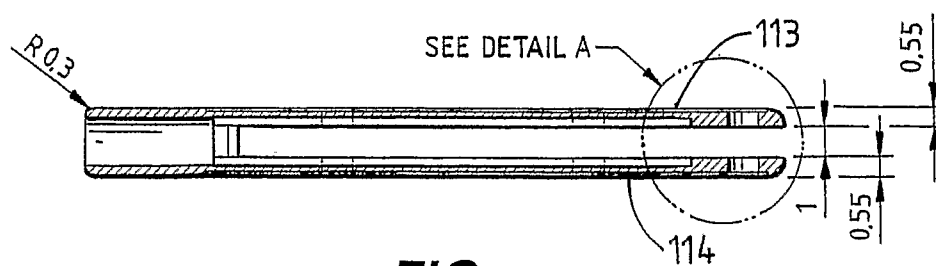


FIG. 13

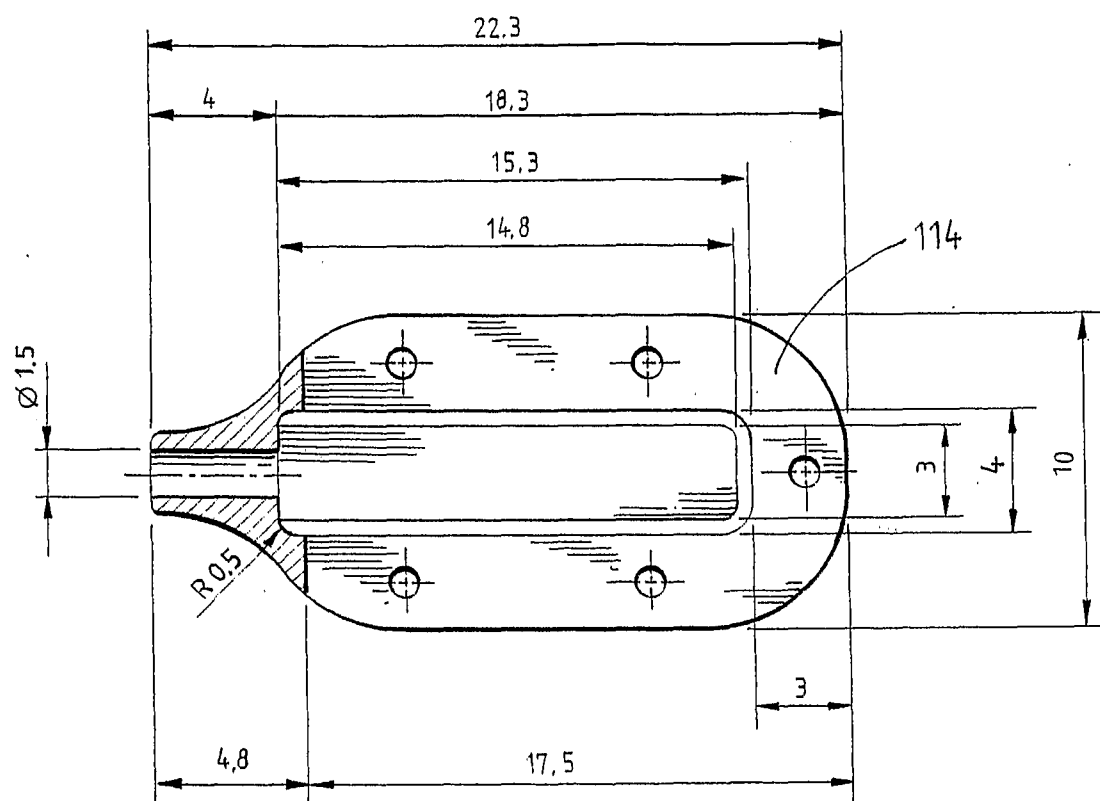


FIG. 14

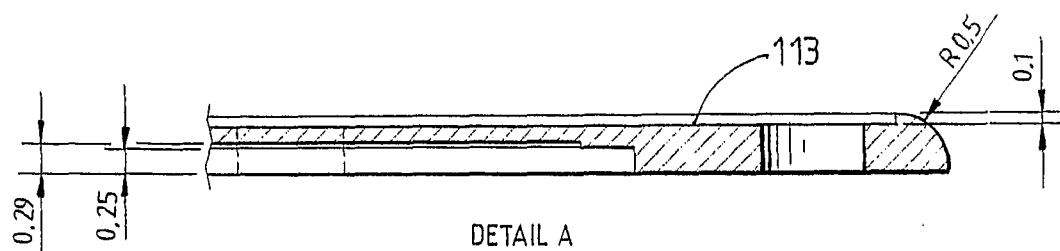


FIG. 15

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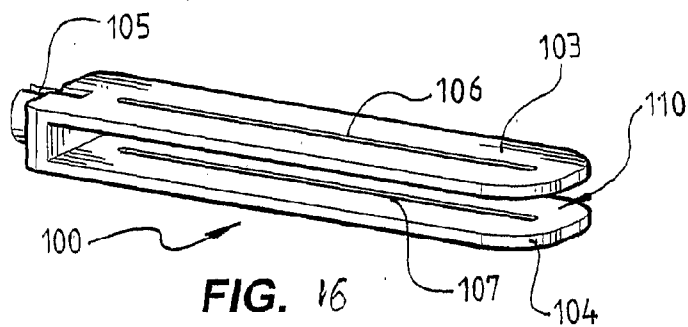


FIG. 16

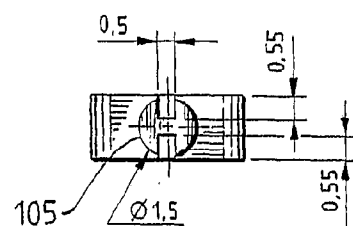


FIG. 17

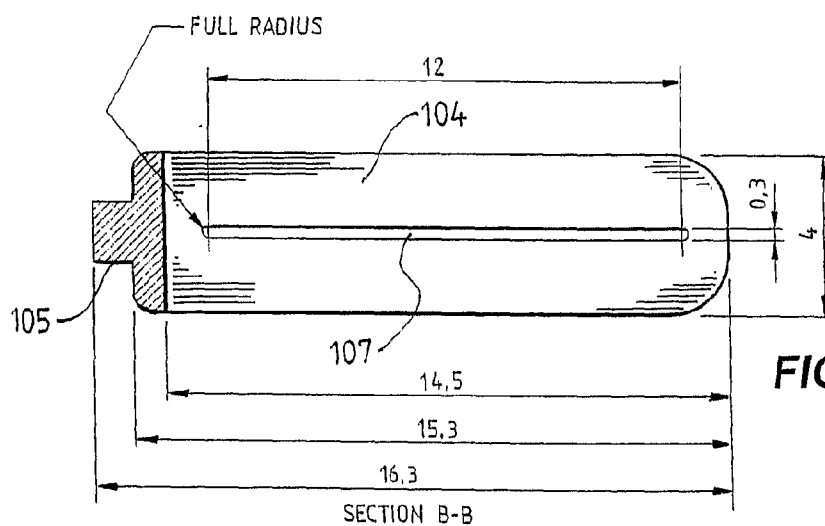


FIG. 18

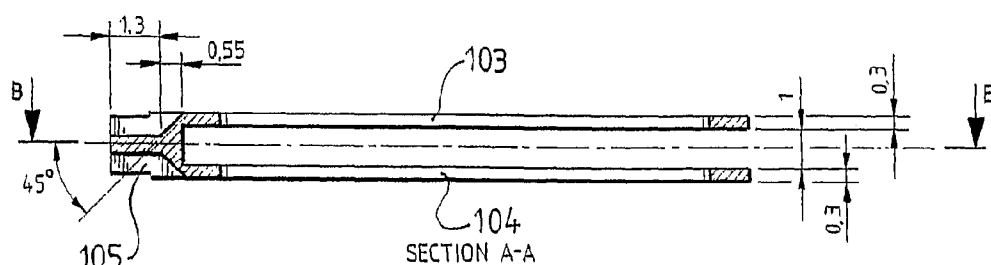


FIG. 19

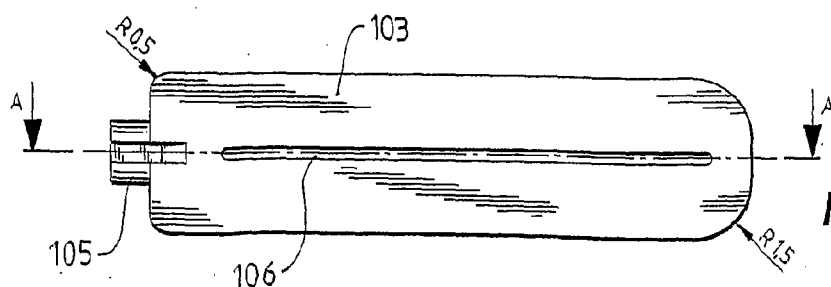


FIG. 20

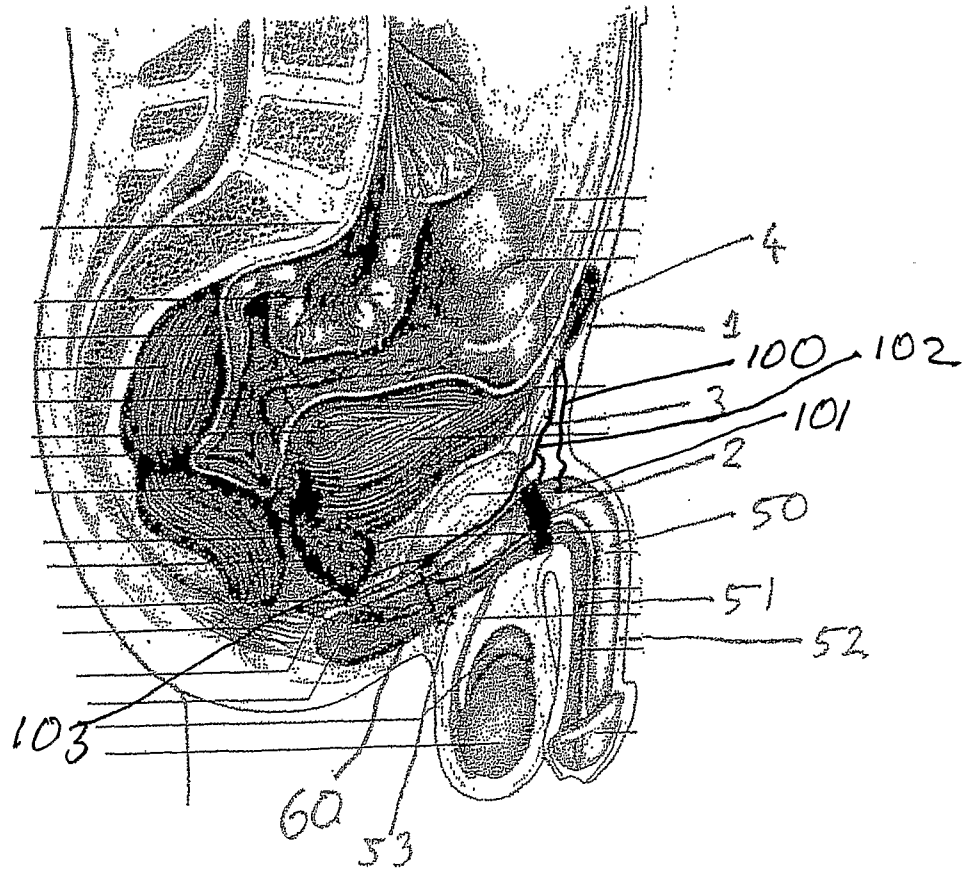
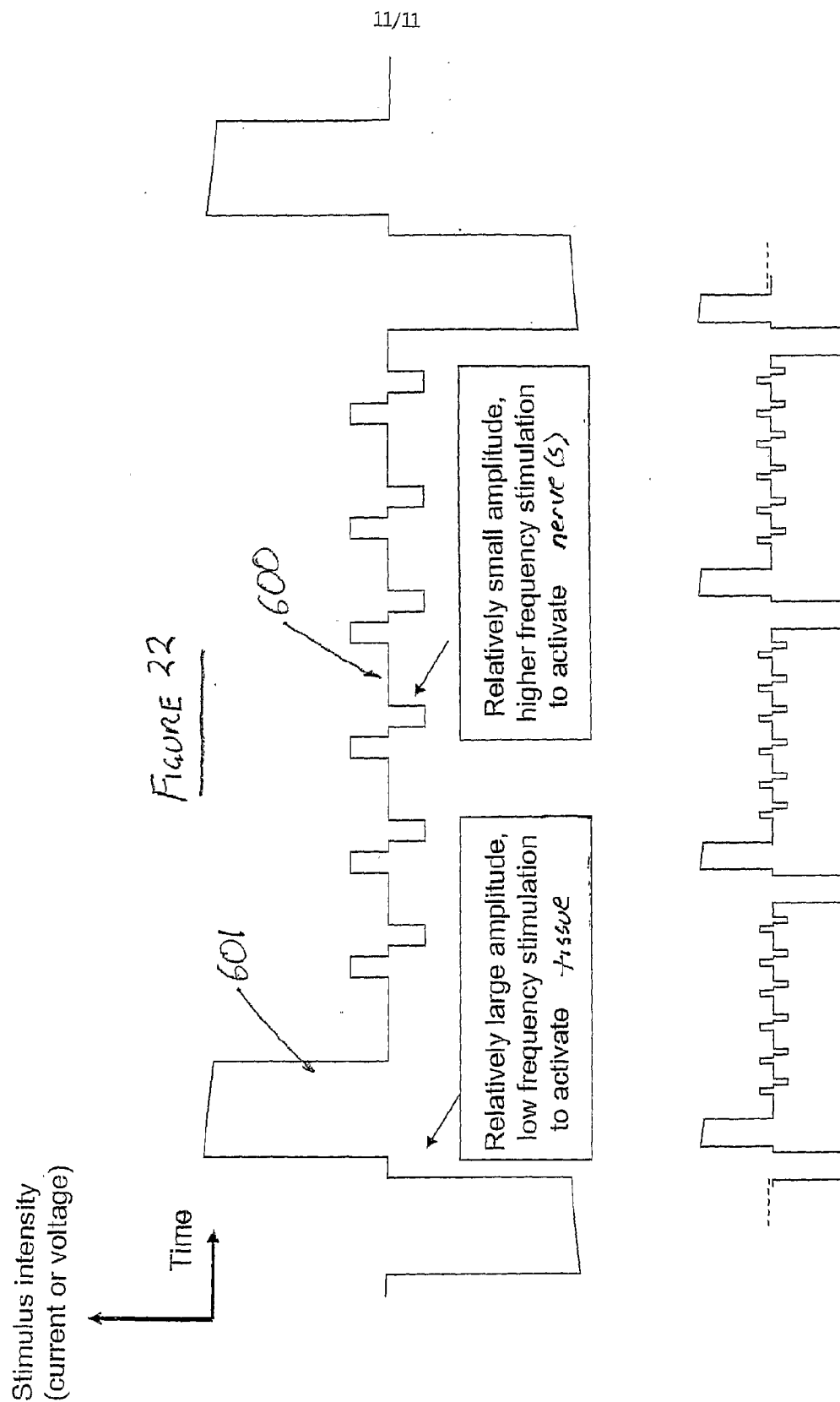


FIGURE 21



INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2007/000525

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

A61N 1/36 (2006.01)

A61F 2/48 (2006.01)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

DWPI +keywords: stimulate, muscle, erection and similar terms

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	Research Disclosure 35649 (356049) December 1993 Whole document	1, 7-10, 17, 23-35, 42, 43, 48, 49



Further documents are listed in the continuation of Box C



See patent family annex

* Special categories of cited documents:	
"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E" earlier application or patent but published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search
13 August 2007

Date of mailing of the international search report
17 AUG 2007

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2007/000525

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

First invention Claims 1-50

Second invention Claims 51-60

See extra sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 1-50

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

Supplemental Box

(To be used when the space in any of Boxes I to VIII is not sufficient)

Continuation of Box No: III

This International Searching Authority has found that there are different inventions as follows:

- Claims 1-50 are directed to an apparatus and method for facilitating an erection by stimulating contractile tissue. It is considered that stimulating contractile tissue to facilitate an erection comprises a first distinguishing feature.
- Claims 51-60 are directed to an apparatus and method for facilitating an erection by stimulating nerves. It is considered that stimulating nerves to facilitate an erection comprises a second distinguishing feature.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

The only feature common to all of the claims is a method of electrically stimulating the body to facilitate an erection. However this concept is not novel in the light of:

US 6,650,943

US 4,585,005

This means that the common feature can not constitute a special technical feature within the meaning of PCT Rule 13.2, second sentence, since it makes no contribution over the prior art.

Because the common feature does not satisfy the requirement for being a special technical feature it follows that it cannot provide the necessary technical relationship between the identified inventions. Therefore the claims do not satisfy the requirement of unity of invention *a posteriori*.