

A TRANSURETHRAL DEVICE

The present invention relates to a transurethral device comprising a transurethral insertion element having an elongate shaft with a free forward end for insertion into the urethra of a living human or animal body and is particularly, although not exclusively, concerned with a transurethral device of the aforementioned type for use in the treatment of erectile dysfunctions such as impotence, priapism and Peyronie's disease in living male human or animal bodies. The invention further relates to a sheath for sheathing of a transurethral insertion element.

Impotence in living male human bodies is the condition in which a male human body is unable to attain or sustain an erect penis for the satisfactory engagement of sexual intercourse. There are numerous documented causes for impotence, for example impotence caused by vasculogenic disorders such as insufficient blood flow to the arteries in the penis or excessive venal outflow. Priapism is a condition characterised by the persistent and often painful erection of the penis while Peyronie's disease is characterised by fibrosis of the cavernous tissue of the penis causing painful and distorted erection.

One aspect of the present invention is directed to erectile dysfunctions such as impotence, priapism and Peyronie's disease which are treatable by the delivery of erectile dysfunction treatment drugs locally to the urethra.

Prior International patent application publications WO95/26158 and WO96/28142 make known transurethral devices for treating erectile dysfunction such as impotence in a living male human body by delivering an erectile dysfunction treatment drug into the urethra of the male human body. These prior art transurethral devices comprise a transurethral insertion element having a drug carrying component part and a plunger component part movable in the drug carrying part and a sheath for sheathing the insertable portion of the transurethral insertion element.

The drug carrying component part comprises an elongate shaft portion for insertion into the urethra of the male human body which presents front and rear axially spaced ends and a handle portion which is connected to the rear end of the shaft portion. The drug carrying component part is provided with an open-ended axial bore which comprises a rearward
5 section of a first width which passes through the handle portion and a forward section of a second width less than the first width which passes through the elongate shaft. The forward section of the axial bore is adapted in use to carry the erectile dysfunction treatment drug.

10 The plunger component part comprises an enlarged head portion and an elongate shaft portion which projects forwardly from the enlarged head portion. The plunger component part is adapted to be inserted forwardly into the bore in the drug carrying component part to a withdrawn position in which the enlarged head portion is partially located in the rearward section of the bore such that a rearward section of the enlarged head portion projects
15 rearwardly from the bore and the elongate shaft portion projects forwardly into the forward section of the axial bore such that the free forward end of the elongate shaft portion is spaced rearwardly of the erectile dysfunction treatment drug.

The sheath of the transurethral device comprises an elongate main body having axially
20 spaced front and rear faces and which is provided with an elongate recess which extends forwardly from an open end in the rear face to a position intermediate the rear and forward faces. The elongate shaft portion of the drug carrying component part is releasably receivable in the recess presented by the sheath to protect the elongate shaft portion from structural damage and/or contamination prior to insertion thereof into the urethra of the
25 male human body.

In use, the user holds the handle of the drug carrying component part in his fingers and removes the sheath to reveal the elongate shaft portion of the drug carrying component part. The elongate shaft portion of the drug carrying component is then inserted into the
30 urethra of the user and the plunger component part depressed forwardly from the withdrawn position into the drug carrying component part to cause the free forward end of

the elongate shaft of the plunger component part to discharge the erectile dysfunction treatment drug forwardly from the axial bore in the drug carrying component part into the urethra.

- 5 While the aforementioned prior transurethral devices successfully provide for the local delivery of an erectile dysfunction treatment drug for, for example, the attainment and sustainment of a penile erection in the case of impotence, Applicants have identified an area in which such devices can be improved. To facilitate insertion of the elongate shaft portion of the drug carrying component part of the previously proposed transurethral
- 10 devices it is recommended that before insertion of the elongate shaft portion of the drug carrying component part into the urethra the user first pass urine to wet the urethra. Clearly this is not always practical. Avoidance of this step, however, can obviously lead to pain on insertion of the elongate shaft portion of the drug carrying component part into the urethra.
- 15 Alternately, the user is provided with a separate supply of lubricant for application to the outer surface of the elongate shaft of the drug carrying component part of the transurethral insertion element after unsheathing thereof. Again, this is not always convenient or practical and moreover the lubricant tends to end up on the hands and clothes of the user. More importantly, this additional step introduces the possibility of contamination of the
- 20 elongate shaft portion of the drug carrying component part of the transurethral insertion element.

The present invention proposes to address this drawback of the hitherto proposed transurethral devices and according to a first aspect of the present invention there is

25 provided a transurethral device for treating erectile dysfunction in a living male human or animal body comprising a transurethral insertion element for carrying an erectile dysfunction treatment agent, the transurethral insertion element comprising an elongate shaft with a free forward end with at least a forward section of the elongate shaft which presents the forward end being adapted for insertion into the urethra of the male human or

30 animal body, means for transferring the erectile dysfunction treatment agent from the transurethral insertion element to the urethra on insertion of the at least a forward section of

the elongate shaft into the urethra and lubricating means for lubricating the outer surface of at least a part of the at least a forward section of the elongate shaft to facilitate insertion of the at least a forward section of the elongate shaft of the transurethral insertion element into the urethra of the human or animal body.

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In embodiments of the invention hereinafter to be described the transurethral device further comprises a sheath for releasably sheathing the at least a forward section of the elongate shaft of the transurethral insertion element with the lubricating means forming part of the sheath.

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According to a second aspect of the invention there is provided a transurethral device comprising a transurethral insertion element having an elongate shaft with a free forward end with at least a forward section of the elongate shaft which presents the forward end adapted for insertion into the urethra of a human or animal body, and a sheath for
15 releasably sheathing the at least a forward section of the elongate shaft of the transurethral insertion element prior to insertion thereof into the urethra of the human or animal body, the sheath being provided with lubricating means for lubricating the outer surface of at least a part of the at least a forward section of the elongate shaft to facilitate insertion of the at least a forward section of the elongate shaft of the transurethral insertion element into the
20 urethra of the human or animal body.

In an embodiment of the invention the lubricating means is adapted to lubricate all or substantially all of the at least a forward section of the elongate shaft.

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In embodiments of the invention hereinafter to be described the lubricating means is adapted to lubricate the outer surface of at least a part of the at least a forward section of the elongate shaft when sheathed in the sheath.

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In embodiments of the invention hereinafter to be described the sheath has a body in which a bore having an open end in an outer surface of the body is provided for releasably

receiving the at least a forward section of the elongate shaft of the transurethral insertion element.

According to a third aspect of the invention there is provided a sheath for a transurethral insertion element having an elongate shaft with a free forward end with at least a forward section of the elongate shaft which presents the forward end adapted for insertion into the urethra of a human or animal body, the sheath having a body in which a bore having an open end in an outer surface of the body is provided for releasably receiving the at least a forward section of the elongate shaft of the transurethral insertion element and being provided with lubricating means for lubricating the outer surface of at least a part of the at least a forward section of the elongate shaft of the transurethral insertion element to facilitate insertion of the at least a forward section of the elongate shaft into the urethra of the human or animal body.

In embodiments of the invention hereinafter to be described the lubricating means comprises a lubricant container in the sheath which under a predetermined condition is able to transfer lubricant in the lubricant container onto the outer surface of at least a part of the at least a forward section of the elongate shaft of the transurethral insertion element.

In an embodiment of the invention hereinafter to be described the lubricant container is a lubricant compartment in the body of the sheath having a boundary wall which is common with at least a portion of the boundary wall of the bore in the body of the sheath and the common boundary wall is able to be brought to an open disposition by application of the predetermined condition whereby lubricant in the lubricant compartment is able to be discharged into the bore in the body of the sheath and onto the outer surface of at least a part of the at least a forward section of the elongate shaft of the transurethral insertion element when received in the bore.

In an embodiment of the invention hereinafter to be described the common boundary wall is so constructed as to be rupturable by application of a predetermined pressure to the outer surface of the body of the sheath for discharge of lubricant from the lubricant compartment

into the bore and onto the outer surface of at least a part of the at least a forward section of the elongate shaft of the transurethral insertion element when received in the bore. The lubricant compartment may be so dimensioned and arranged in the body of the sheath that the common boundary wall surrounds at least a part of the at least a forward section of the elongate shaft of the transurethral insertion element when received in the bore. The lubricant compartment may, in fact, be so dimensioned and arranged in the body of the sheath that the common boundary wall surrounds the at least a forward section of the elongate shaft of the transurethral insertion element when received in the bore so that all of the insertable portion of the elongate shaft is lubricated.

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In another embodiment of the invention hereinafter to be described the lubricant container is an open-ended tube having annular forward and rearward ends for location in the bore in the body of the sheath for at least a forward part of the at least a forward section of the elongate shaft to pass through or be received in, the tube having an inner surface for receiving lubricant and further being of such dimensions that lubricant is able to be coated on the outer surface of the at least a forward part of the at least a forward section of the elongate shaft by movement of the at least a forward section of the elongate shaft in the bore relative to the tube.

20 In an embodiment of the invention the at least a forward part of the at least a forward section of the elongate shaft is a forward portion of the at least a forward section of the elongate shaft and the forward portion is able to pass through the tube with the remainder of the at least a forward section of the elongate shaft being disposable in the tube. Thus, all, or substantially all, of the outer surface of the at least a forward section is able to be lubricated.

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In an embodiment of the invention hereinafter to be described the tube is locatable in the bore in the body of the sheath for the at least a forward part of the at least a forward section of the elongate shaft to pass therethrough and the annular forward end of the tube is provided with a radially inwardly directed annular flange for forming a sealing ring around the elongate shaft of the transurethral insertion element when received in the bore in the

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body of the sheath for preventing or substantially preventing transfer of lubricant from the inner surface of the tube to the outer surface of the at least a forward part of the at least a forward section of the elongate shaft on passage through the tube. Lubricant is thus essentially restricted to being transferred from the inner surface of the tube to the outer surface of the at least a forward part of the at least a forward section of the elongate shaft on withdrawal of the elongate shaft from the bore. Preferably, the at least a forward part of the at least a forward section of the elongate shaft is a forward portion of the at least a forward section of the elongate shaft with the remainder of the at least a forward section of the elongate shaft being disposable in the tube whereby withdrawal of the elongate shaft from the bore results in all or substantially all of the outer surface of the insertable portion being lubricated.

In an embodiment of the invention according to its first and second aspects hereinafter to be described the transurethral insertion element comprises a collar having a forward end connected to a rear end of the elongate shaft with a forward section of the collar which presents the forward end thereof being receivable in the bore in the body of the sheath on insertion of the elongate shaft into the bore. The forward section of the collar has a width which is greater than the width of the elongate shaft and so selected that the peripheral outer surface thereof is adapted to form a close fit with the adjacent boundary wall of the bore when received therein. Moreover, the forward end of the collar is adapted to abut the annular rearward end of the tube when the elongate shaft is inserted into the bore. A further sealing ring is thus able to be formed by the collar.

In an embodiment of the invention hereinafter to be described the tube is of a compressible material and has an outer surface profile which is so dimensioned relative to the bore that the tube is displaceable from an uncompressed state to a compressed state on location of the tube in the bore for an expansion fit of the tube in the bore. As an example, the tube can have a frusto-conical outer surface profile

In an embodiment of the invention according to its third aspect hereinafter to be described the transurethral insertion element comprises a collar having a forward end which is

connected to a rear end of the elongate shaft and which is presented by a forward section of the collar having a width which is greater than the width of the elongate shaft, the bore is adapted for receiving the forward section of the collar when the elongate shaft is received in the bore with the peripheral outer surface of the forward section of the collar forming a close fit with the adjacent boundary wall of the bore and the tube is so dimensioned as to be locatable in the bore for the forward end of the collar to abut the annular rearward end of the tube for forming a further sealing ring.

By way of example embodiments of the present invention will now be described with reference to the accompanying Figures of drawings in which:-

Fig. 1 is an exploded view of a transurethral device for the treatment of erectile dysfunction such as impotence in a living male human body in accordance with a first embodiment of the invention comprising a transurethral insertion element for insertion into the urethra of the male human body having a drug carrying part and a plunger part and a sheath for sheathing the insertable portion of the transurethral insertion element;

Fig. 2 is a cross-sectional view of the transurethral device of Fig. 1 in an assembled state;

Fig. 3 is a side view of the transurethral device of Fig. 1 in the assembled state;

Fig. 4 is a plan view from below of the transurethral device of Fig. 1 in the assembled state;

Fig. 5 is a plan view from above of the transurethral device of Fig. 1 in the assembled state;

Fig. 6 is an exploded view of a transurethral device for the treatment of erectile dysfunction such as impotence in a living male human body in accordance with a second embodiment of the invention comprising a transurethral insertion element for insertion into the urethra of the male human body having a drug carrying part and a plunger part and a sheath for sheathing the insertable portion of the transurethral insertion element comprising a transparent body part and an open-ended tubular part;

Fig. 7 is a cross-sectional view of the transurethral device of Fig. 6 in an assembled state;

Fig. 8 is a side view of the transurethral device of Fig. 6 in the assembled state;

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Fig. 9 is a plan view from below of the transurethral device of Fig. 6 in the assembled state; and

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Fig. 10 is a plan view from above of the transurethral device of Fig. 6 in the assembled state.

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Figs 1 to 5 of the drawings show a transurethral device 10 for treating erectile dysfunction such as impotence in a male human patient or body according to a first embodiment of the present invention. As can be seen from Fig. 1 of the drawings which shows the transurethral device 10 in an unassembled state, the transurethral device 10 comprises a transurethral insertion element 1 for insertion in the urethra of the male human body having a drug carrying part 3 and a plunger part 5 and a sheath 7 for storage of the transurethral insertion element 1 prior to use thereof. Preferably, the aforementioned separable parts of the transurethral device 10 are moulded as one-piece bodies from a plastics material.

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The drug carrying part 3 presents an elongate shaft 9 having a free forward end 11 adapted to be insertable into the urethra of the male human body, a finger grip 13 for the male human body to hold the transurethral insertion element 1 and a collar 14 which connects the forward end of the finger grip 13 to the rear end of the elongate shaft 9. As shown in Fig. 2, an axial bore 15 extends through the drug carrying part 3 between a forward open end 17 at the forward end 11 of the elongate shaft 9 and a rear open end 19 in the rear end of the finger grip 13. The bore 15 is stepped into a forward section 16 of a first width which extends rearwardly from the forward open end 17 through the elongate shaft 9 and a rearward section 18 of a second width which is greater than the first width which extends forwardly from the rear open end 19 through the finger grip 13. The forward section 16 of the bore 15 is adapted in use to carry an erectile dysfunction treatment drug (not shown)

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which is to be transferred to the urethra of the male human body by the plunger part 5 as hereinafter to be described.

Referring to Figs 1 and 2, the plunger part 5 of the transurethral insertion element 1 presents an elongate shaft 21 having a free forward end 23 and an enlarged head 25 connected to the rear end of the elongate shaft 21. When the transurethral insertion element 1 is assembled the elongate shaft 21 and enlarged head 25 of the plunger part 5 are respectively received in the forward section 16 and rearward section 18 of the bore 15 in the drug carrying part 3.

Referring now specifically to Fig. 2, the sheath 7 is provided with a bore 27 sized to releasably receive the elongate shaft 9 and collar 14 of the drug carrying part 3 until such time as the transurethral insertion element 1 is to be used. The elongate shaft 9 is thus kept free from damage and/or contamination. As will be described hereinafter in more detail, the sheath 7 is further provided with a lubricant containing compartment 29 adapted in use to coat the outer surface of the elongate shaft 9 of the drug carrying part 3 with lubricant prior to insertion thereof in the urethra of the male human body.

Assembly of the transurethral device 10 preparatory to use thereof will now be described with reference to Figs 2 to 5.

First, the transurethral insertion element 1 is assembled by inserting the plunger part 5 into the rear open end 19 of the axial bore 15 in the drug carrying part 3 to a withdrawn position in which the enlarged head 25 is positioned partially in the rearward section 18 of the bore 15 so as to project rearwardly from the rear open end 19 and the elongate shaft 21 projects forwardly into the forward section 16 of the axial bore 15 but with the forward end 23 of the elongate shaft 21 being disposed rearwardly of the erectile dysfunction treatment drug carried in the forward section 16 of the bore 15 in the drug carrying part 3.

Second, the sheath 7 and transurethral insertion element 1 are assembled by inserting the elongate shaft 9 and collar 14 of the drug carrying part 3 into the bore 27 presented by the

sheath 7 until the forward end of the finger grip 13 abuts the rearward end of the sheath 7. In the present embodiment the whole of the elongate shaft 9 of the drug carrying part 3 is received in the bore 27 of the sheath 7. It will be appreciated by those versed in the art, though, that if the length of the elongate shaft 9 is longer than that portion of the shaft to be inserted into the urethra then it is sufficient that at least the insertable length of the elongate shaft 9 is received in the bore 27 of the sheath 7.

As already stated hereinabove, the sheath 7 is provided with a lubricant containing compartment 29. As can be seen by reference to Fig. 2, a boundary wall 31 of the lubricant containing compartment 29 also serves as a portion of the boundary wall of the bore 27 in the sheath 7. The common boundary wall 31 is constructed so as to be rupturable or otherwise openable on application of a predetermined condition thereto, in this case a predetermined pressure being applied to the outer surface of the sheath 7 which when transmitted to the common boundary wall 31 causes the common boundary wall 31 to be brought to an open disposition. Bringing the common boundary wall 31 to the open disposition results in the lubricant being able to be discharged from the compartment 29 into the bore 27 in the sheath 7 and onto the adjacent outer surface of the elongate shaft 9 of the drug carrying part 3.

The type of lubricant contained in the compartment 29 will depend on the material which presents the outer surface of the insertable length of the elongate shaft 9 of the drug carrying component part 3. Typically, the lubricant will be in the form of a gel, for example cellulose gels. Where the outer surface of the insertable length of the elongate shaft 9 of the drug carrying part 3 is hydrophilic, though, water or saline could be used as the lubricant. Whatever lubricant is used, it should not have a deleterious effect on the efficacy of the erectile dysfunction treatment drug.

The lubricant can be coated over the whole of the outer surface of the elongate shaft 9 of the drug carrying part 3 by manipulation of the transurethral insertion element 1 relative to the sheath 7. To this end, the collar 14 of the drug carrying part 3 acts as a sealing ring to prevent leakage of the lubricant from the bore 27 of the sheath 7. Alternatively, the

lubricant containing compartment 29 can be so dimensioned and juxtaposed to the bore 27 in the sheath 7 that discharge of the lubricant from the compartment 29 automatically coats the elongate shaft 9 of the drug carrying part 3 bounded by the bore 27. For example, the lubricant containing compartment 29 could be formed so as to bound substantially all of the bore adjacent the elongate shaft 9 of the drug carrying part 3.

While it is preferable that substantially all of the insertable length of the elongate shaft 9 of the drug carrying part 3 be lubricated, insertion of the elongate shaft 9 into the urethra of the male human body will still be more comfortable even if only a part of the insertable length is lubricated, for example a forward section of the elongate shaft 9.

In use, the elongate shaft 9 of the drug carrying part 3 is firstly lubricated in the manner outlined in the preceding paragraphs. The transurethral device 1 is then held by the finger grip 13 and withdrawn from the sheath 7 to reveal the lubricated elongate shaft 9 of the drug carrying part 3. The elongate shaft 9 of the drug carrying part 3 is inserted into the urethra of the male human body and the plunger part 5 depressed forwardly to a depressed position in which the forward end of the enlarged head 25 abuts the step between the forward and rearward sections 16, 18 of the bore 15 in the drug carrying part 3. Depression of the plunger part 5 to the depressed position results in the free forward end 23 of the elongate shaft 21 of the plunger part 5 pushing the erectile dysfunction treatment drug out of the forward open end 17 of the bore 15 in the drug carrying part 3 into the urethra of the male human body thereby in the case of impotence to give a sustainable penile erection.

In Figs 6 to 10 of the drawings there is shown a transurethral device 110 for treating erectile dysfunction such as impotence in a living male human body according to a second embodiment of the present invention.

Referring first to Fig. 6 which shows the transurethral device 110 in an unassembled state, the transurethral device 110 corresponds to the transurethral device 10 hereinabove described with reference to Figs 1 to 5 in that the transurethral device 110 comprises a transurethral insertion element 101 and a sheath 107. Moreover, the transurethral insertion

element 101 corresponds to the transurethral insertion element 1 of the transurethral device 10 hereinabove described with reference to Figs 1 to 5.

The transurethral insertion element 101 of the transurethral device 110 accordingly firstly
5 comprises a drug carrying part 103 which presents an elongate shaft 109 having a free forward end 111 for insertion into the urethra of the male human body, a finger grip 113 for holding the transurethral insertion element 101 and a collar 114 which connects the forward end of the finger grip 113 to the rear end of the elongate shaft 109. Furthermore, as shown in Fig. 7, an axial bore 115 extends through the drug carrying part 103 between a
10 forward open end 117 in the forward end 111 of the elongate shaft 109 and a rear open end 119 in the rear end of the finger grip 113, the bore 115 being stepped into a forward section 116 of a first width which extends rearwardly through the elongate shaft 109 from the forward open end 117 and a rearward section of a second width greater than the first width which extends forwardly through the finger grip 113 from the rear open end 119. The
15 forward section 116 of the bore 115 is adapted in use to carry an erectile dysfunction treatment drug (not shown) which is to be transferred from the bore 115 into the urethra of the male human body as will hereinafter be described.

The transurethral insertion element 101 secondly comprises a plunger part 105 for
20 discharging the erectile dysfunction treatment drug from the drug carrying part 103 into the urethra of the male human body, the plunger part 105 presenting an elongate shaft 121 having a free forward end 123 sized to be receivable in the forward section 116 of the axial bore 115 in the drug carrying part 103 and an enlarged head 125 connected to the rear end of the elongate shaft 121 and sized to be receivable in the rearward section 118 of the axial
25 bore 115 in the drug carrying part 103.

Referring now to Figs 6 to 8, the sheath 107 comprises a body part 120 in which is provided an axial bore 127 having an open end in the rear end of the body part 120 and an open-ended tubular part 130 having a slight conical outer surface profile which is insertable
30 into the bore 127 in the body part 120 of the sheath 107. As can be seen by particular reference to Fig. 7, the forward end of the tubular part 130 presents a radially inwardly

directed annular flange 140 the purpose of which will become apparent hereinafter. The tubular part 130 is made of a compressible material and is so dimensioned relative to the bore 127 in the body part 120 of the sheath 107 that on insertion of the tubular part 130 into the bore 127 in the body part 120 of the sheath 107 the tubular part 130 is displaced
5 inwardly from an uncompressed state to a compressed state.

Assembly of the transurethral device 110 will now be described with reference to Figs 7 to 10 of the drawings.

10 First, the plunger part 105 of the transurethral insertion element 101 is inserted forwardly into the axial bore 115 in the drug carrying part 103 to a withdrawn position in which the enlarged head 125 is partially positioned in the rearward section 118 of the bore 115 such that the rear end of the head 125 projects rearwardly from the rear open end 119 of the bore 115 and the elongate shaft 121 projects forwardly into the forward section 116 of the bore
15 115 such that the forward end 123 of the elongate shaft 121 is disposed rearwardly of the erectile dysfunction treatment drug carried in the forward section 116 of the bore 115.

Secondly, the tubular part 130 of the sheath 107 is inserted into the bore 127 in the body part 120 of the sheath 107.

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Third and finally, the transurethral insertion element 101 is assembled to the sheath 107 by inserting the elongate shaft 109 and a forward section of the collar 114 of the drug carrying part 103 into the axial bore 127 in the body part 120 of the sheath 107 with the elongate shaft 109 passing through the tubular part 130.

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Prior to assembly of the transurethral insertion element 101 and sheath 107 as aforesaid the inner surface of the tubular part 130 is coated with lubricant. As shown in Fig. 7, when the transurethral device 110 is assembled a lubricant layer 150 is interposed between the inner surface of the tubular part 130 of the sheath 107 and the adjacent outer surface of the
30 elongate shaft 109 of the drug carrying part 103 of the transurethral insertion element 101. The radially inwardly directed annular flange 140 presented at the forward end of the

tubular part 130 contacts the outer surface of the elongate shaft 109 of the drug carrying part 103 on insertion thereof into the bore 127 in the body part 120 of the sheath 107. The flange thus acts to inhibit transfer of the lubricant from the inner surface of the tubular part 130 to the outer surface of that part of the elongate shaft 109 of the drug carrying part 103 which passes forwardly of the flange 140 on insertion of the elongate shaft 109 of the drug carrying part 103 into the bore 127 in the body part 120 of the sheath 107.

In effect, the inner surface and flange 140 of the tubular part 130 define boundary walls of a lubricant container which surrounds the adjacent outer surface of the elongate shaft 109 of the drug carrying part 103 when the transurethral device 110 is assembled. With this in mind, the outer circumferential surface of the forward section of the collar 114 of the drug carrying part 103 which projects into the bore 127 in the body part 120 of the sheath 107 when the transurethral device 110 is assembled forms a close fit with the adjacent boundary wall of the bore 127 and the forward end of the collar 114 abuts the rear end of the tubular part 130. The collar 114 therefore also acts to contain the lubricant in the "lubricant container".

When the transurethral device 110 is required to be used by the male human body, the male human body withdraws the transurethral insertion element 101 from the sheath 107 by gripping the finger grip 113 and pulling the transurethral insertion element 101 rearwardly with respect to the sheath 107. Withdrawal of the transurethral insertion element 101 from the sheath 107 results in the lubricant being transferred from the inner surface of the tubular part 130 of the sheath 107 onto the outer surface of the elongate shaft 109 of the drug carrying part 103 withdrawn through the tubular part 130.

Although the illustrated embodiment is so constructed and arranged that the whole of the outer surface of the elongate shaft 109 of the drug carrying component 103 is withdrawn through the tubular part 130 to be coated with lubricant, it will be appreciated by those skilled in the art that it is not strictly necessary for the whole of the outer surface of the elongate shaft 109 of the drug carrying part 103 to be coated with lubricant for facilitating insertion thereof into the urethra of the male human body. For example, if the whole

length of the elongate shaft 109 of the drug carrying part 103 is not required to be inserted into the urethra then only the insertable length could be coated with lubricant. Even then insertion will be facilitated provided at least a portion of the insertable length of the elongate shaft 109 of the drug carrying part 103 is coated with lubricant, for example a forward section of the shaft 109.

Once the elongate shaft 109 of the drug carrying part 103 has been inserted into the urethra of the male human body the plunger part 105 is depressed forwardly from the withdrawn position to a depressed position in which the forward end of the enlarged head 125 abuts the step defining the transition between the forward and rearward sections 116, 118 of the bore 115 in the drug carrying part 103. Forward depression of the plunger part 105 to the depressed position causes the forward end 123 of the elongate shaft 121 of the plunger part 105 to discharge the erectile dysfunction treatment drug from the forward section 116 of the bore 115 in the drug carrying part 103 into the urethra of the male human body thereby in the case of impotence to give a sustainable penile erection.

It can therefore be seen that in accordance with the present invention there is provided a transurethral device for the treatment of erectile dysfunction in a living male human or animal body which has the advantage of including means which facilitate insertion of the insertable portion of the transurethral insertion element thereof into the urethra of the male human or animal body without the need for (i) the human or animal body to pass urine first, or (ii) introducing an additional step for lubricating the insertable portion of the transurethral insertion element having an attendant possibility of contamination of the insertable portion. It is to be understood, though, that the instant invention is not limited to transurethral devices used for drug delivery but has broad application to the general field of transurethral devices.



Claims:

1. A transurethral device (10; 110) for treating erectile dysfunction in a living male human or animal body comprising a transurethral insertion element (1; 101) for carrying an
5 erectile dysfunction treatment agent, the transurethral insertion element comprising an elongate shaft (9; 109) with a free forward end (11; 111) with at least a forward section of the elongate shaft which presents the forward end being adapted for insertion into the urethra of the male human or animal body, and means (5; 105) for transferring the erectile dysfunction treatment agent from the transurethral insertion element to the urethra on
10 insertion of the at least a forward section of the elongate shaft into the urethra **characterised in that** the transurethral device further comprises lubricating means (29; 130) for lubricating the outer surface of at least a part of the at least a forward section of the elongate shaft to facilitate insertion of the at least a forward section of the elongate shaft of the transurethral insertion element into the urethra of the human or animal body.
- 15 2. A transurethral device according to claim 1 further comprising a sheath (7; 107) for releasably sheathing the at least a forward section of the elongate shaft of the transurethral insertion element **characterised in that** the lubricating means forms part of the sheath.
- 20 3. A transurethral device according to claim 2, **characterised in that** the lubricating means is adapted to lubricate the outer surface of at least a part of the at least a forward section of the elongate shaft when sheathed in the sheath.
- 25 4. A transurethral device (10; 110) comprising a transurethral insertion element (1; 101) having an elongate shaft (9; 109) with a free forward end (11; 111) with at least a forward section of the elongate shaft which presents the forward end adapted for insertion into the urethra of a human or animal body, and a sheath (7; 107) for releasably sheathing the at least a forward section of the elongate shaft of the transurethral insertion element
30 prior to insertion thereof into the urethra of the human or animal body **characterised in that** the sheath contains lubricating means (29; 130) for lubricating the outer surface of at



least a part of the at least a forward section of the elongate shaft to facilitate insertion of the at least a forward section of the elongate shaft of the transurethral insertion element into the urethra of the human or animal body.

5 5. A transurethral device according to claim 4, **characterised in that** the lubricating means (29; 130) is for lubricating the outer surface of at least a part of the at least a forward section of the elongate shaft when sheathed in the sheath.

10 6. A transurethral device according to any one of claims 2 to 5, **characterised in that** the lubricating means comprises a lubricant container (29; 130) in the sheath which under a predetermined condition is able to transfer lubricant in the lubricant container onto the outer surface of at least a part of the at least a forward section of the elongate shaft of the transurethral insertion element.

15 7. A transurethral device according to claim 6, **characterised in that** the sheath has a body (120) in which a bore (27; 127) having an open end in an outer surface of the body is provided for releasably receiving the at least a forward section of the elongate shaft of the transurethral insertion element, **that** the lubricant container is a lubricant compartment (29) in the body of the sheath having a boundary wall (31) which is common with at least a
20 portion of the boundary wall of the bore in the body of the sheath **and that** the common boundary wall is able to be brought to an open disposition by application of the predetermined condition whereby lubricant in the lubricant compartment is able to be discharged into the bore in the body of the sheath and onto the outer surface of at least a part of the at least a forward section of the elongate shaft of the transurethral insertion
25 element when received in the bore.

8. A transurethral device according to claim 7, **characterised in that** the common boundary wall is so constructed as to be rupturable by application of a predetermined pressure to the outer surface of the body of the sheath for discharge of lubricant from the
30 lubricant compartment into the bore and onto the outer surface of at least a part of the at



least a forward section of the elongate shaft of the transurethral insertion element when received in the bore.

9. A transurethral device according to claim 7 or 8, characterised in that the
5 lubricant compartment is so dimensioned and arranged in the body of the sheath that the common boundary wall surrounds at least a part of the at least a forward section of the elongate shaft of the transurethral insertion element when received in the bore.

10. A transurethral device according to claim 9, characterised in that the lubricant
10 compartment is so dimensioned and arranged in the body of the sheath that the common boundary wall surrounds the at least a forward section of the elongate shaft of the transurethral insertion element when received in the bore.

11. A transurethral device according to claim 6, characterised in that the sheath has
15 a body (120) in which a bore (27; 127) having an open end in an outer surface of the body is provided for releasably receiving the at least a forward section of the elongate shaft of the transurethral insertion element, that the lubricant container is an open-ended tube (130) having annular forward and rearward ends for location in the bore in the body of the sheath for at least a forward part of the at least a forward section of the elongate shaft to pass
20 through or be received in, the tube having an inner surface for receiving lubricant and further being of such dimensions that lubricant is able to be coated on the outer surface of the at least a forward part of the at least a forward section of the elongate shaft by movement of the at least a forward section of the elongate shaft in the bore relative to the tube.

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12. A transurethral device according to claim 11, characterised in that the tube is locatable in the bore in the body of the sheath for the at least a forward part of the at least a forward section of the elongate shaft to pass therethrough and that the annular forward end of the tube is provided with a radially inwardly directed annular flange (140) for forming a
30 sealing ring around the elongate shaft of the transurethral insertion element when received in the bore in the body of the sheath for preventing or substantially preventing transfer of



lubricant from the inner surface of the tube to the outer surface of the at least a forward part of the at least a forward section of the elongate shaft on passage through the tube whereby lubricant is transferable from the inner surface of the tube to the outer surface of the at least a forward part of the at least a forward section of the elongate shaft on withdrawal of the at
5 least a forward section of the elongate shaft from the bore.

13. A transurethral device according to claim 12, characterised in that the at least a forward part of the at least a forward section of the elongate shaft is a forward portion of the at least a forward section of the elongate shaft and that the remainder of the at least a
10 forward section of the elongate shaft is disposable in the tube whereby the at least a forward section is able to be lubricated on withdrawal of the elongate shaft from the bore.

14. A transurethral device according to claim 12 or 13, characterised in that the sealing ring is a first sealing ring, that the transurethral insertion element comprises a
15 collar having a forward end connected to a rear end of the elongate shaft, that a forward section of the collar which presents the forward end thereof is receivable in the bore in the body of the sheath on insertion of the elongate shaft into the bore, that the forward section of the collar has a width which is greater than the width of the elongate shaft and so selected that the peripheral outer surface thereof is able to form a close fit with the adjacent
20 boundary wall of the bore when received therein and that the forward end of the collar is able to abut the annular rearward end of the tube when the elongate shaft is inserted into the bore to form a second sealing ring.

15. A transurethral device according to any one of claims 11 to 14, characterised in
25 that the tube is of a compressible material and has an outer surface profile which is so dimensioned relative to the bore that the tube is displaceable from an uncompressed state to a compressed state on location of the tube in the bore for an expansion fit of the tube in the bore.

30 16. A transurethral device according to claim 15, characterised in that the tube has a frusto-conical outer surface profile.



17. A sheath (7; 107) for a transurethral insertion element (1; 101) having an elongate shaft (9; 109) with a free forward end (11; 111) with at least a forward section of the elongate shaft which presents the forward end adapted for insertion into the urethra of a human or animal body, the sheath having a body (120) in which a bore (27; 127) having an open end in an outer surface of the body is provided for releasably receiving the at least a forward section of the elongate shaft of the transurethral insertion element **characterised in that** the sheath is provided with lubricating means (29; 130) for lubricating the outer surface of at least a part of the at least a forward section of the elongate shaft of the transurethral insertion element to facilitate insertion of the at least a forward section of the elongate shaft into the urethra of the human or animal body.

18. A sheath according to claim 17, **characterised in that** the lubricating means (29; 130) is for lubricating the outer surface of at least a part of the at least a forward section of the elongate shaft of the transurethral insertion element when received in the bore.

19. A sheath according to claim 17 or 18, **characterised in that** the lubricating means comprises a lubricant container (29; 130) in the sheath which under a predetermined condition is able to transfer lubricant in the lubricant container onto the outer surface of at least a part of the at least a forward section of the elongate shaft of the transurethral insertion element when received in the bore in the body of the sheath.

20. A sheath according to claim 19, **characterised in that** the lubricant container is a lubricant compartment (29) in the body of the sheath having a boundary wall (31) which is common with at least a portion of the boundary wall of the bore in the body of the sheath **and that** the common boundary wall is able to be brought to an open disposition by application of the predetermined condition whereby lubricant in the lubricant compartment is able to be discharged into the bore in the body of the sheath and onto the outer surface of at least a part of the at least a forward section of the elongate shaft of the transurethral insertion element when received in the bore.



21. A sheath according to claim 20, **characterised in that** the common boundary wall is so constructed as to be rupturable by application of a predetermined pressure to the outer surface of the body of the sheath for discharge of lubricant from the lubricant compartment into the bore and onto the outer surface of at least a part of the at least a forward section of the elongate shaft of the transurethral insertion element when received in the bore.

22. A sheath according to claim 20 or 21, **characterised in that** the lubricant compartment is so dimensioned and arranged in the body of the sheath that the common boundary wall surrounds at least a part of the at least a forward section of the elongate shaft of the transurethral insertion element when the elongate shaft is received in the bore.

23. A sheath according to claim 22, **characterised in that** the lubricant compartment is so dimensioned and arranged in the body of the sheath that the common boundary wall surrounds the at least a forward section of the elongate shaft of the transurethral insertion element when the elongate shaft is received in the bore.

24. A sheath according to claim 19, **characterised in that** the lubricant container is an open-ended tube having annular forward and rearward ends for location in the bore in the body of the sheath for at least a forward part of the at least a forward section of the elongate shaft to pass through or be received in, the tube having an inner surface for receiving lubricant and further being of such dimensions that lubricant is able to be coated on the outer surface of the at least a forward part of the at least a forward section of the elongate shaft by movement of the elongate shaft in the bore relative to the tube.

25. A sheath according to claim 24, **characterised in that** the tube is locatable in the bore in the body of the sheath for the at least a forward part of the at least a forward section of the elongate shaft to pass therethrough and that the annular forward end of the tube is provided with a radially inwardly directed annular flange (140) for forming a sealing ring around the elongate shaft of the transurethral insertion element when received in the bore in the body of the sheath for preventing or substantially preventing transfer of lubricant from the inner surface of the tube to the outer surface of the at least a forward part of the at



least a forward section of the elongate shaft on passage through the tube whereby lubricant is transferable from the inner surface of the tube to the outer surface of the at least a forward part of the at least a forward section of the elongate shaft on withdrawal of the elongate shaft from the bore.

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26. A sheath according to claim 25, wherein the at least a forward part of the at least a forward section of the elongate shaft is a forward portion of the at least a forward section of the elongate shaft **characterised in that** the dimensions of the bore and tube are so selected that the tube is locatable in the bore for disposal of the remainder of the at least a forward section in the tube whereby the at least a forward section is able to be lubricated on withdrawal of the elongate shaft from the bore.

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27. A sheath according to claim 25 or 26, wherein the transurethral insertion element comprises a collar having a forward end which is connected to a rear end of the elongate shaft and which is presented by a forward section of the collar having a width which is greater than the width of the elongate shaft **characterised in that** the bore is adapted for receiving the forward section of the collar when the elongate shaft is received in the bore with the peripheral outer surface of the forward section of the collar forming a close fit with the adjacent boundary wall of the bore **and that** the tube is so dimensioned as to be locatable in the bore for the forward end of the collar to abut the annular rearward end of the tube for forming a further sealing ring.

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28. A sheath according to any one of claims 24 to 27, **characterised in that** the tube is of a compressible material and has an outer surface profile which is so dimensioned relative to the bore that the tube is displaceable from an uncompressed state to a compressed state on location of the tube in the bore for an expansion fit of the tube in the bore.

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29. A sheath according to claim 28, **characterised in that** the tube has a frusto-conical outer surface profile.

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