Methods and apparatus are provided for brachytherapy treatment of prostate disease for use in conjunction with needles containing a plurality of radioactive seeds. The apparatus comprises a housing and plunger assembly operable by a single clinician. The plunger is coupled to the housing, so that when the apparatus is actuated the needle is retracted against the plunger and the plurality of radioactive seeds is ejected.
METHODS AND APPARATUS FOR BRACHYTHERAPY TREATMENT OF PROSTATE DISEASE

REFERENCE TO RELATED APPLICATIONS


FIELD OF THE INVENTION

[0002] This invention relates to improved apparatus and methods for the treatment of prostate cancer. More particularly, the present invention provides improved methods and apparatus for administering brachytherapy.

BACKGROUND OF THE INVENTION

[0003] Excluding non-melanoma skin cancers, prostate cancer is the most common cancer afflicting American men. The American Cancer Society estimates that over 180,000 new cases will be diagnosed in the U.S. in the year 2000 alone, and that nearly 32,000 people will die from the disease. Prostate cancer is second only to lung cancer as the leading cause of cancer death in men, accounting for roughly 11%.

[0004] Prostate cancer is defined as malignant tumor growth within the prostate gland. Its cause is unknown, although high dietary fat intake and increased testosterone levels are believed to be contributory factors. A letter scale ("A" through "D"), which accounts for the location of the cancer, is commonly used to classify the stage of disease. In Stage A, the tumor is not palpable, but is detectable in microscopic biopsy. Stage B is characterized by a palpable tumor confined to the prostate. By Stage C, the tumor extends locally beyond the prostate with no distant metastasis. By Stage D, cancer has spread to the regional lymph nodes or has produced distant metastasis.

[0005] In the early stages, prostate cancer is most commonly treated by prostate removal or by brachytherapy. More advanced cases are treated by hormonal manipulation or orchietomy to reduce testosterone levels and curb spreading of the disease, by chemotherapy, or by external beam radiation therapy.

[0006] With regard to treatment of early stage prostate cancer, the state of the art has several drawbacks. Radical prostatectomy is often recommended for treatment of localized stage A and B prostate cancers. Under general or spinal anesthesia, an incision is made through a patient’s abdomen or perineal area, and the diseased prostate is removed. The procedure is lengthy, especially if a lymph node dissection is simultaneously performed, and requires a hospital stay of 2-5 days. Possible complications include impotence and urinary incontinence.

[0007] Internal radiation therapy or brachytherapy has recently been modified and holds great promise for the treatment of early stage prostate cancer. Radioactive pellets or seeds of, for example, iodine-125, gold-198, palladium-103, ytterbium-169, or iridium-192, are deposited directly into the prostate through needle placement. Imaging tests, such as transrectal ultrasound, CT scans, or MRI, are used to accurately guide placement of the radioactive material. Advantageously, radiation is administered directly to the prostate with less damage to surrounding tissues, requiring a significantly smaller radiation dosage as compared to external beam radiation therapy. Furthermore, the procedure need only be performed once. Complications include a lower, yet still significant, incidence of impotence and urinary incontinence, compared to prostate removal procedures.

[0008] The radioactive seeds are placed inside thin needles, which are inserted through the skin of the perineum (area between the scrotum and anus) into the prostate. U.S. Pat. No. 5,928,130 to Schmidt provides a slightly modified example of such a needle device. Each needle is slowly retracted with a spinning motion by a first practitioner while a plunger within the needle, and proximal of the radioactive seeds, is held stationary by a second practitioner. The plunger keeps the seeds in place during retraction of the needle, while rotation of the needle during retraction prevents jamming of the seeds while delivering the seeds in a line within the prostate.

[0009] The seeds, which are permanently implanted, give off radiation for weeks or months. Their presence causes little discomfort, and they are left in the prostate after decay of the radioactivity. For about a week following needle insertion, patients may experience pain in the perineal area, and urine may have a red-brown discoloration.

[0010] Although, when performed correctly, radioactive seed implantation may provide several benefits, compared to prostate removal and other techniques, current surgical apparatus and methods for delivering the seeds to target locations within the prostate are somewhat crude and are subject to practitioner error. The procedure requires two practitioners working cooperatively to deliver the seeds. The depth to which the plunger is inserted into the needle, in the loaded and advanced states, is critical but crudely measured. The plunger and needle may accidentally move relative to one another during needle insertion or seed delivery, causing improper positioning of deposited seeds. The needle is somewhat flexible and should be inserted quickly to minimize bending at its distal tip, but this is often not done due to inexperience or technical ability of the practitioners, or to avoid potential relative movement between the plunger and the needle.

[0011] Attempts have been made to address various aspects of these concerns. For example, U.S. Pat. No. 4,815,449 to Horowitz describes an absorbable member with seeds spaced within the member to facilitate proper spacing during delivery. U.S. Pat. No. 4,700,692 to Baumgartner describes apparatus for delivering all of the seeds simultaneously. PCT document WO 99/20337 to Rydell describes a gun-like apparatus for delivering seeds once the needle has been inserted into the prostate.

[0012] While each of these devices may provide some benefit over the prior art, none satisfactorily addresses the shortcomings of current techniques. In view of the drawbacks associated with previously-known methods and apparatus for brachytherapy, it would be desirable to provide methods and apparatus that overcome such drawbacks.

[0013] It further would be desirable to provide methods and apparatus that allow efficient preparation of the apparatus for therapeutic administration.
It still further would be desirable to provide methods and apparatus for administering brachytherapy that require only one medical practitioner.

It further would be desirable to provide methods and apparatus that yield easy measurement and maintenance of plunger depth within the needle.

It would also be desirable to provide methods and apparatus for brachytherapy that allow rapid insertion of the needle while maintaining the distance between the needle and plunger.

**SUMMARY OF THE INVENTION**

In view of the foregoing, it is an object of the present invention to provide methods and apparatus for brachytherapy that overcome drawbacks associated with previously-known methods and apparatus.

It is also an object of the present invention to provide methods and apparatus that allow efficient preparation of the apparatus for therapeutic administration.

It is another object to provide methods and apparatus for brachytherapy that require only one medical practitioner.

It is yet another object to provide methods and apparatus that yield easy measurement and maintenance of plunger depth within the needle.

It still further is an object of the present invention to provide methods and apparatus for brachytherapy that allow rapid insertion of the needle while maintaining the distance between the needle and plunger.

These and other objects of the present invention are accomplished by providing methods and apparatus for brachytherapy treatment of prostate cancer comprising a specialized housing that maintains needle/plunger spacing, provides easy measurement of plunger depth within the needle, requires only one practitioner to operate, and enables rapid needle insertion. The plunger is either permanently or selectively fixed with respect to the housing, while the needle is removably coupled to the housing. Either the plunger or the housing wall is threaded to receive the needle. Measurement indicia on the apparatus simplify determination of plunger depth within the needle. Optionally, a locking mechanism may be used to maintain plunger depth during needle insertion. To deliver seeds, the needle is rotated while the housing is held stationary, causing the needle to retract along the screw thread.

In a preferred embodiment, the needle is rotated manually, and includes a mechanism for first ejecting a seed-retaining plug disposed in a distal end of the needle. Alternatively, the needle may attach to a swivel that rotates the needle by pulling it proximally along the screw thread. In a still further embodiment, a pull tab may be used to rotate the needle.

Methods of using the present invention are also provided.

**BRIEF DESCRIPTION OF THE DRAWINGS**

Additional objects and advantages of the invention will be apparent from the following description, the accompanying drawings and the appended claims, in which:
perineum $P_e$ into prostate $P$, where needle $56$ is retracted and seeds $60$ are delivered to the patient.

[0043] With reference to FIG. 2, a previously known seed delivery method is described in greater detail. Needle $56$ has proximal end $62$, sharpened distal end $64$, and a lumen extending therebetween. Proximal end $62$ comprises hub $66$ for easy grasping of the needle. The opening at the distal tip of needle $56$ is initially filled with a material that prevents seeds $60$ from falling out of the needle, and may comprise, for example, bone wax that melts when placed inside the body. The needle lumen typically is filled in an alternating pattern of seeds $60$ and spacers $68$.

[0044] Once a required number of seeds have been loaded, plunger $58$ is inserted into proximal end $62$ of needle $56$ and is advanced distally until it abuts the proximal-most seed. Plunger $58$ comprises grip $70$ at its proximal end. The distance from the distal end of grip $70$ to the distal end of the plunger is equal to the length of needle $56$. Thus, since seeds $60$ and spacers $68$ are of known length, measurement of $D_1$, the distance plunger $58$ extends proximally of needle $56$ in the loaded configuration, provides verification of the number of seeds $60$ located within the needle lumen, as seen in FIG. 2A.

[0045] Ultrasound probe $52$ provides signals that are converted by a previously known ultrasound system to display ultrasonic image $72$ of base plane $BP$, which is located at a tangent to the distal surface of prostate $P$. All positions within the prostate are determined relative to base plane $BP$. With seeds $60$ loaded into needle $56$ and the distance $D_1$ verified, the needle, seeds, and plunger $58$ are inserted through guide block $54$ and into the patient until needle $56$ appears as target $T$ on ultrasonic image $72$ and extends about a centimeter distal of base plane $BP$, as depicted in FIG. 2B. The apparatus is then retracted until target $T$ disappears (FIG. 2C) and is once again advanced until target $T$ just reappears (FIG. 2D). All the while, distance $D_1$ is maintained.

[0046] Once needle $56$ is aligned with base plane $BP$, a distance $D_2$ between the proximal face of guide block $54$ and the proximal face of hub $66$ is established, as shown in FIG. 2E. $D_2$ serves as the reference distance for determining insertion depth for all subsequent needle insertions. A first medical practitioner then holds needle $56$ stationary while a second medical practitioner advances the first seed $60$ to the distal tip of the needle with plunger $58$, as depicted in FIG. 2F. The advancement distance equals the length $BW$ of the plug in the distal tip of the needle.

[0047] Finally, the second medical practitioner holds plunger $58$ stationary while the first practitioner rotates and proximally retracts needle $56$ to sew the seeds in a line within prostate $P$, as shown in FIG. 2G. The needle and plunger are then removed from the patient, and the procedure is repeated at other locations as necessary.

[0048] With reference now to FIGS. 3 and 4, a first embodiment of apparatus constructed in accordance with the present invention is described. Apparatus $100$ comprises housing $102$, plunger $104$, needle $106$, and optional lock $108$. Lock $108$ is configured to be received in slot $110$ of needle $106$. Needle $106$ further comprises lumen $107$, an actuator comprising male screw thread $112$, and measurement indicia $113$. Housing $102$ comprises lumen $114$, in which plunger $104$ is rigidly fixed, threaded bore $116$ with female screw thread $118$, and standard bore $120$. When assembled, male thread $112$ of needle $106$ engages female thread $118$ of housing $102$, and plunger $104$ extends into lumen $107$ of needle $106$.

[0049] A method of using apparatus $100$ in accordance with the principles of the present invention is now described. Needle $106$, loaded with seeds $60$ and spacers $68$ in lumen $107$, is inserted through bore $120$ until male thread $112$ of needle $106$ just mates with female thread $118$ of bore $116$.

[0050] At this point, plunger $104$ extends partially within lumen $107$ of needle $106$, so that plunger $104$ just contacts the proximal-most seed $60$. Also, slot $110$ of needle $106$ is just distal of the opening to bore $120$. Lock $108$ is removably received within slot $110$ and ensures that plunger $104$ is not advanced distally with respect to needle $106$ until the needle is inserted within a patient’s prostate. Lock $108$ ensures that distance $D_1$ between the proximal end of needle $106$ and proximal base $122$ of bore $116$ (which is roughly equal to the length of bore $116$) is maintained during insertion. Since $D_1$ is positively maintained during insertion, the apparatus of the present invention should advantageously cause medical practitioners to be less reticent about rapid insertion of the needle into a patient.

[0051] Measurement indicia $113$ of needle $106$ permit easy determination of distance $D_1$, and, thus, verification of the number of seeds $60$ contained within lumen $107$ of needle $106$. As an illustrative example, $D_1$ is such that the proximal-most indicator mark $113$ extends beyond the distal end of housing $102$. If this marking is ‘0’, the proximal end of needle $106$ is in contact with proximal base $122$ of bore $116$. If it is ‘1’, there is one centimeter of separation, etc.

[0052] After insertion of the needle into the patient, lock $108$ is removed, thereby allowing relative movement between plunger $104$ and needle $106$. Initially, needle $106$ is held stationary while housing $102$ is rotated to advance the distal-most seed $60$ to the tip of needle $106$. Then, housing $102$ is held stationary while needle $106$ is rotated. This causes needle $106$ to retract proximally along thread $118$ while plunger $104$ remains stationary, thereby controllably sewing seeds $60$ in a row in the prostate. Since the sewing motion is simplified, compared to prior art apparatus $50$, only one practitioner is required to perform the procedure.

[0053] The distance $D_1$ may be altered as needed by altering the length of bore $116$ and, thus, the length of housing $102$. Alternatively, bore $116$ may be of a standard length in excess of that required for $D_1$. Needle $106$ then may comprise multiple slots $110$ along its length to receive lock $108$. The distance $D_1$ then may be fixed at a variety of lengths.

[0054] Referring now to FIG. 5, an alternative embodiment of the present invention is disclosed. Apparatus $130$ comprises housing $132$, plunger $134$, needle $136$, and lock $138$. Lock $138$ is configured to be received in slot $140$ of needle $136$. Needle $136$ further comprises lumen $137$, female screw thread $142$ along the walls of the proximal portion of its lumen, and measurement indicia (not shown). Plunger $134$ comprises male screw thread $144$ along its proximal end. Housing $132$ comprises lumen $146$, in which plunger $134$ is rigidly fixed, and bore $148$.

[0055] Needle $136$, loaded with seeds $60$ and spacers $68$, is inserted through bore $148$ until female thread $142$ of
needle 136 just mates with male thread 144 of plunger 134. Thus, apparatus 130 is similar to apparatus 100, except that needle 136 threadingly engages plunger 134, rather than the housing.

[0056] With reference to FIGS. 6 and 7, a further alternative embodiment of the present invention is detailed. Apparatus 150 comprises housing 152, plunger 154, needle 156, and lock 158. Lock 158 is configured to be received in slot 160 of needle 156. Needle 156 further comprises lumen 157, male screw thread 162, measurement indicia 163, and swivel 164 including cord 166. Housing 152 comprises lumen 168, in which plunger 134 is rigidly fixed; threaded bore 170 with female screw thread 172; and a standard bore (not shown) similar to bore 120 of apparatus 100. Housing 152 further comprises cord bore 174 through which cord 166 passes out of housing 152.

[0057] In use, cord 166 is threaded through cord bore 174 and the male and female screw threads are engaged as described hereinabove with reference to apparatus 100. Needle 156 then may be retracted proximally with respect to housing 152 by holding the housing stationary and pulling cord 166 proximally. The needle rotates and retracts within the screw thread, while swivel 164 moves proximally in bore 168, but does not rotate.

[0058] Referring now to FIGS. 8 and 9, a still further alternative embodiment of the present invention is described. Apparatus 180 comprises housing 182, plunger 184, needle 186, swivel 188, and lock 190. Lock 190 is configured to be removably received in slot 192 of needle 186. Housing 182 comprises lumen 194, in which plunger 184 is rigidly fixed; threaded bore 196 with female screw thread 198; and a standard bore (not shown) similar to bore 120 of apparatus 100. Housing 182 is formed in two halves 200 and 202 joined at hinge 204. Hinge 204 preferably is a ‘living hinge’ as may be constructed using polymers, such as polypropylene, and previously known manufacturing techniques. Needle 186 further comprises lumen 187, male screw thread 189, measurement indicia 207, and swivel attachment 208. Syringe swivel 188 comprises swivel attachment 210, bore 212, and enlarged proximal end 214, and is formed in two halves 216 and 218 joined at hinge 220. As with hinge 204, hinge 220 preferably comprises a living hinge.

[0059] Housing 182 and syringe swivel 188 are opened at hinges 204 and 220, respectively, so that swivel attachments 208 and 210, and the male and female screw threads, engage each other. The housing and syringe swivel are then closed. After insertion into a patient, needle 186 may be retracted proximally with respect to housing 182 by holding the housing stationary and retracting enlarged end 214 of syringe swivel 188 proximally. Needle 186 rotates and retracts within the screw thread while syringe swivel 188 moves proximally but does not rotate.

[0060] With reference to FIGS. 10-12, yet another alternative embodiment of the present invention is described. Apparatus 230 comprises housing 232, plunger 234, needle 236, pull tab 238, and lock 240. Lock 240 is configured to be received in slot 242 of needle 236. Needle 236 further comprises lumen 237, male screw thread 244, and measurement indicia 245. Housing 232 comprises lumen 246, in which plunger 234 is rigidly fixed, threaded bore 248 with female screw thread 250, standard bore 252, and slot lumen 254 configured to receive pull tab 238. Slot lumen 254 is preferably located just off center of the radial axis of housing 232 and communicates with bore 252. Pull tab 238 comprises grip 256 and female threads 258.

[0061] Needle 236, loaded with seeds 60 and spacers 68, is inserted through bore 252 into threaded bore 248 until male thread 244 of needle 236 mates with both female screw thread 250 of housing 232 and female threads 258 of pull tab 238. As most clearly illustrated in FIG. 11, needle 236 then may move relative to housing 232 simply by holding housing 232 stationary and pulling or pushing pull tab 238. Pulling tab 238 causes needle 236 to rotate and proximally retract in a controlled fashion along screw thread 250 of housing 232, and along threads 258 of pull tab 238, thereby sewing the seeds along the needle track.

[0062] Whereas the preceding embodiments contemplate that the needle include a thread that acts as an actuator in conjunction with a thread in the housing to retract the needle, if would be preferable to provide embodiments adapted to accept commercially available brachytherapy needles. Two such embodiments, which work in accordance with the principles of the present invention set forth hereinabove, are now described.

[0063] Referring now to FIGS. 13 and 14, a preferred embodiment of the present invention suitable for commercial manufacture is described. Apparatus 260 includes housing 261 having spiral groove 262 on its interior surface, knob 263 rigidly coupled to actuator 264, needle coupling 265 and stop mechanism 266 coupled to plunger 267. Plunger 267 is disposed within the lumen of seed-laden needle 275 when needle 275 is coupled to needle coupling 265. In this embodiment, plunger 267 is selectively set to a predetermined seed length using stop mechanism 266, before needle 275 is attached to needle coupling 265.

[0064] Needle coupling 265 is disposed for sliding translation and rotation in central bore 268 of actuator 264, and includes pin 269 that extends through elongated slot 270 of actuator 264 and extends into spiral groove 262. Actuator 264 is rotatably disposed in housing 261. Rotation of knob 263 causes rotation of actuator 264, thereby driving pin 269 along spiral groove 262 and elongated slot 270. This in turn causes needle coupling to be rotated and advanced or retracted through central bore 268 of actuator 264. When a seed-laden needle is coupled to needle coupling 265, rotation of knob 263 causes the needle to be rotated and retracted into housing 261. Plunger 267, which remains stationary during needle retraction, causes the seeds to be ejected from the distal tip of the needle.

[0065] Stop mechanism 266 permits the number of seeds to be varied from needle to needle during a particular procedure, and includes a coarse adjustment for the number of seeds used in a given needle, and a fine adjustment feature that permits the plug at the distal end of the needle to be ejected without changing the position of the distal tip of the needle. Stop mechanism includes stop body 271 having ratchet 272 slidable disposed in lumen 273, wherein the travel is limited by pin 274 that extends into elongated slot 276 (this subassembly is shown in exploded view in the upper right hand portion of FIG. 14B). Stop body 271 includes a series of partial circumference through-wall slits 277 arranged along its length at predetermined distances.
(e.g., 1 cm apart), and includes fiducial markings F on the upper surface of the stop body (see FIG. 13) aligned with slits 277.

[0066] Distal end 278 of stop body 271 extends through rear cover 279 of housing 261 and window 280 of lock 281, and is affixed to collar 282. Rear cover 279 includes notch 283 that accepts tab 284 of lock 281 and spring 285. Tab 284 includes button 286 and is biased upward by spring 285. Button 286 permits lock 281 to be depressed to permit stop body 271 to be advanced distally through window 280. Spring 285 causes the lower edge of window 280 to engage one of slits 277 and a corresponding one of teeth 287 of ratchet 272 when button 286 is released.

[0067] Stop body knob 288 is affixed to proximal end 289 of stop body 271. Distal end 290 of ratchet 272 extends through spring 291 and is rigidly coupled to ratchet knob 292. Spring 291 biases ratchet knob 292 in a proximal direction. Teeth 287 of ratchet 272 include sloped proximal edges 293. The sloped proximal edges of teeth 287 permit ratchet 272 to be advanced through window 280 of lock 281 in the distal direction by urging ratchet knob 292 in the distal direction, while simultaneously maintaining engagement between a selected slit 278 in stop body 271 and lock 281. This in turn permits plunger 267 to be advanced one unit in the distal direction, e.g., to eject the needle plug, while maintaining the position of the distal tip of stationary.

[0068] Operation of apparatus 260 is now described. To use apparatus 260, the clinician rotates knob 263 to advance needle coupling 265 to its distal-most position, and depresses button 286 to ensure that lock 281 is disengaged from ratchet 272 and ratchet knob 292 is biased in the proximal direction by spring 291. The clinician then sets the seed length by depressing button 286 and advancing or retracting stop body 271 using stop body knob 288 until the desired fiducial mark F is aligned with the endface of rear cover 279. Button 286 then is released to capture the corresponding slit in stop body 271.

[0069] A seed-laden needle is then slid proximal-end first over plunger 267 and the luer of the needle affixed to needle coupling 265, for example, using luer threads (not shown) disposed in distal end of needle coupling 265. The needle and apparatus of the present invention then is inserted into the patient's prostrate using a needle guide and an rapid insertion technique. Once the needle position is confirmed, e.g., using ultrasound, the clinician urges ratchet knob 292 in the distal direction to eject the plug from the distal tip of the needle. In particular, when ratchet knob 292 is advanced, window 280 of lock 281 rides along the sloped edge of tooth 288 and locks into the next proximal-most tooth 288 of ratchet 272, while stop-body 271 remains engaged with lock 281. This step is similar to that illustrated in FIG. 2F.

[0070] Once the plug is ejected from the distal end of the needle, housing 261 is held stationary by the clinician in one hand while knob 263 is rotated by the other. Rotation of knob 263 causes actuator 264 to rotate within housing 261, thereby causing pin 269 to be retracted along spiral groove 262 in housing 261. This in turn causes needle coupling 265 to be retracted into central bore 268 of actuator 264, thereby also rotating the needle attached to needle coupling. Because plunger 267 remains fixed at the depth selected on stop body relative to the housing, rotation and retraction of the needle causes the seeds to be ejected into the prostrate. Accordingly, a single clinician can implant seeds faster and more accurately than the conventional method using two clinicians.

[0071] When all the seeds in the needle have been implanted, the needle is removed from the patient and knob 263 is rotated in the reverse direction to fully expose needle coupling 265. The spent needle is removed from needle coupling 265, and then the process described above is repeated for subsequent needles, until the procedure is completed. Apparatus 260 preferable can be manufactured from low-cost plastic components with few machined or stamped metal components, and is therefore disposable after use for a single patient.

[0072] Referring now to FIGS. 15A and 15B, an alternative embodiment of the apparatus suitable for commercial manufacture is described. Apparatus 300 is less preferred than the embodiment of FIGS. 13 and 14, and employs several machined components. Accordingly, the embodiment of FIG. 15 may be more suitable for manufacture from metallic alloys, and therefore autoclavable for repeated use.

[0073] Apparatus 300 comprises many of the components employed in the embodiment of FIGS. 13 and 14, including housing 301 having spiral groove 302 on its interior surface, knob 303 rigidly coupled to actuator 304, needle coupling 305 and stop mechanism 306 coupled to plunger 307. Plunger 307 is disposed within the lumen of a seed-laden needle when such a needle is coupled to needle coupling 305. As in the previous embodiment, plunger 307 is selectively set to a predetermined seed length using stop mechanism 306, before the needle is attached to needle coupling 305.

[0074] Needle coupling 305 is disposed for sliding translation and rotation in central bore 308 of actuator 304, and includes pin 309 that extends through elongated slot 310 of actuator 304 and extends into spiral groove 302. Actuator 304 is rotatably disposed in housing 301, so that rotation of knob 303 causes rotation of actuator 304, thereby driving pin 309 along spiral groove 302 and elongated slot 310. This in turn causes needle coupling to be rotated and advanced or retracted through central bore 308 of actuator 304. When a seed-laden needle is coupled to needle coupling 305, rotation of knob 303 causes the needle to be rotated and retracted into housing 301. Plunger 307, which remains stationary during needle retraction, causes the seeds to be ejected from the distal tip of the needle.

[0075] Stop mechanism 306 performs the same function as stop mechanism 266 of the embodiment of FIGS. 13 and 14 by permitting the number of seeds to be varied from needle to needle during a particular procedure. This embodiment also includes a coarse adjustment for the number of seeds used in a given needle, and a fine adjustment feature that permits the plug at the distal end of the needle to be ejected without changing the position of the distal tip of the needle.

[0076] Stop mechanism 306 includes stop body 311 having threaded rod 312 extending therethrough. Stop body 311 includes a series of partial circumference through-wall slits 313 arranged along its length at predetermined distances (e.g., 1 cm apart), and includes fiducial markings F on the upper surface of the stop body aligned with slits 313. Stop body also includes a longitudinally-oriented slot that permits threaded pawl 314 to engage the threads of threaded rod 312.
Distal end 315 of stop body 311 extends through rear cover 319 of housing 301 and window 320 of lock 321, and is affixed to collar 322. Rear cover 319 includes notch 323 that accepts upper and lower tabs 324 and 325 of lock 321, spring 326, and pawl 314. Upper tab 324 serves as a button and is biased upward by spring 326. Upper tab 324 permits lock 321 to be depressed to permit stop body 311 to be advanced distally through window 320. Spring 326 causes the lower edge of window 320 to engage one of slits 313, and for pawl 314 to engage threaded rod 312, when the upper tab is released.

Distal end 328 of threaded rod 312 is affixed to sleeve 329. Sleeve 329 is coupled to cap 330, which is disposed in bore 331 in stop knob 332. Cap 330 is keyed to the shape of bore 331, so that rotation of stop knob 332 causes rotation of cap 330, sleeve 329 and threaded rod 312. Collar 334 is affixed to proximal end 335 of stop body 311, and includes circumferential groove 336. Stop knob 332 includes pin 337 that extends into groove 336, thereby permitting rotation of stop knob 332, but not translation. Spring 338 is captured on sleeve 329 between collar 334 and cap 330, and biases cap 330 in a proximal direction.

Rotation of stop knob 332 causes rotation of cap 332, sleeve 329 and threaded rod 312. Because threaded rod 312 is threadedly engaged with pawl 314 by the biasing action of spring 326, rotation of stop knob 332 causes threaded rod 312 to advance distally, thereby causing plunger 307 to advance in the distal direction. Accordingly, after the needle has been inserted into the patient, stop knob 332 may be rotated to eject the plug at the distal end, while maintaining the position of the distal tip of stationary.

Operation of apparatus 300 is similar to that of the embodiment of FIGS. 13 and 14, and is now described. To use apparatus 300, the clinician rotates knob 303 to advance needle coupling 305 to its distal-most position, and depresses upper tab 324 to ensure that lock 321 is disengaged from slit 313 and pawl 314 is disengaged from threaded rod 312, whereby cap 330 is biased in the proximal direction by spring 338. The clinician then sets the needed length by depressing upper tab 324 of lock 321 and advancing or retracting stop body 311 using stop knob 332 until the desired fiducial mark F is aligned with the endface of rear cover 319. Upper tab 324 then is released to capture the corresponding slit in stop body 311, and so that pawl 314 engages threaded rod 312.

A seed-laden needle is then slid proximal-end first over plunger 307 and the luer of the needle affixed to needle coupling 305, for example, using luer threads (not shown) disposed in distal end of needle coupling 305. The needle and apparatus of the present invention then is inserted into the patient's prostrate using a needle guide and an rapid insertion technique. Once the needle position is confirmed, e.g., using ultrasound, the clinician rotated stop knob 332 to advance threaded rod 312 and plunger 307 to eject the plug from the distal tip of the needle.

Once the plug is ejected from the distal end of the needle, housing 301 is held stationary by the clinician in one hand while knob 303 is rotated by the other. Rotation of knob 303 causes actuator 304 to rotate within housing 301, thereby causing pin 309 to be retracted along spiral groove 302 in housing 301. This in turn causes needle coupling 305 to be retracted into central bore 308 of actuator 304, thereby also rotating the needle attached to needle coupling. Because plunger 307 remains fixed at the depth selected on stop body relative to the housing, rotation and retraction of the needle causes the seeds to be ejected into the prostate.

When all the seeds in the needle have been implanted, the needle is removed from the patient and knob 303 is rotated in the reverse direction to fully expose needle coupling 305. The spent needle is removed from needle coupling 305, and then the process described above is repeated for subsequent needles, until the procedure is completed.

Although particular embodiments of the present invention have been described above in detail, it will be understood that this description is merely for purposes of illustration. Specific features of the invention are shown in some drawings and not in others; this is for convenience only, and any feature may be combined with another in accordance with the invention. Further variations will be apparent to one skilled in the art in light of this disclosure and are intended to fall within the scope of the appended claims.

What is claimed is:

1. Apparatus for performing brachytherapy with a needle having a lumen containing a plurality of seeds and a distal tip, the apparatus comprising:
   a housing having a bore;
   a plunger coupled to the housing, the plunger adapted to be received within the lumen of the needle; and
   an actuator disposed within the bore and coupled to the needle, the actuator configured to retract the needle within the bore so that the plunger ejects the plurality of seeds from the distal tip.

2. The apparatus of claim 1 wherein the housing further includes a spiral thread disposed along an interior surface of the bore.

3. The apparatus of claim 2 wherein the actuator comprises a mating thread disposed on an exterior surface of the needle, the mating thread engaging the spiral thread disposed along the interior of the bore.

4. The apparatus of claim 1 further comprising a lock configured to selectively restrict motion of the plunger relative to the needle.

5. The apparatus of claim 4 wherein the needle further comprises a slot distal of the mating thread, and the lock is removably received within the slot.

6. The apparatus of claim 3, wherein the housing further comprises a cord bore extending into the bore, the apparatus further comprising:
   a swivel coupled to the proximal end of the needle; and
   a cord coupled to the swivel and extending through the cord bore.

7. The apparatus of claim 3 further comprising a first swivel attached to the proximal end of the needle.

8. The apparatus of claim 7 further comprising a syringe swivel slidingly received within the bore of the housing, the syringe swivel coupled to the first swivel.

9. The apparatus of claim 8 wherein the housing comprises a first half and a second half, and a hinge joining the first half to the second half.
10. The apparatus of claim 9 wherein the hinge comprises a living hinge.

11. The apparatus of claim 3 wherein the housing further comprises a slot lumen, the slot lumen in communication with the lumen.

12. The apparatus of claim 11 further comprising a pull tab adapted to extend through the slot lumen to engage the needle.

13. The apparatus of claim 12 wherein the pull tab further comprises threads configured to engage the mating thread.

14. The apparatus of claim 1 further comprises measurement indicia for determining a depth of the plunger within the lumen.

15. The apparatus of claim 2 wherein actuator comprises:
   a tubular member disposed for rotation in the bore, the actuator having an elongated slot and a central bore;
   a needle coupling disposed for rotation and translation in the central bore;
   a pin affixed to the needle coupling, extending through the elongated slot in the tubular member, and engaged in the spiral groove; and
   a knob affixed to the tubular member,

wherein rotation of the knob causes the tubular member to urge the pin along the spiral groove and retract the needle coupling within the central bore.

16. The apparatus of claim 15 further comprising a stop mechanism that permits the plunger to be coupled to the housing with in a predetermined relation.

17. The apparatus of claim 15 wherein the stop mechanism further comprises means for advancing the plunger relative to the housing while retaining the needle in fixed position relative to the housing.

18. A method of ejecting seeds from a needle having a lumen containing a plurality of seeds and a distal tip, the method comprising:

   providing apparatus comprising a housing having a bore, a plunger disposed within the bore and coupled to housing, the plunger having a distal end adapted to be disposed within the lumen of the needle;

   coupling the needle to the apparatus so that the distal end of the plunger is received within the lumen of the needle until the distal end of the plunger contacts a distal-most of the plurality of seeds; and

   actuating the apparatus to retract the needle within the bore of the housing, while the plunger maintains the plurality of seeds stationary with respect to the housing, relative motion between the needle and the plunger causing the plurality of seeds to be ejected from the lumen.

19. The method of claim 18 wherein actuating the apparatus further comprises rotating the needle during retraction of the needle.

20. The method of claim 19 further comprising, prior to actuating the apparatus to retract the needle, actuating the apparatus to advance the plunger distally with respect to the needle and advance a proximal-most one of the plurality of seeds relative to the distal tip of the needle.

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