A semi-automatic brachytherapy loading assembly is disclosed that includes a setting group for positioning at least one of any isotope seed and a spacer, a loading group operatively engaging the setting group for depositing the least one of an isotope seed and a spacer, a viewing member for visualizing the at least one of an isotope seed and a spacer, and a seed receiving device holding group positioned to pass the at least one of an isotope seed and a spacer to a seed receiving device.
SEMI-AUTOMATIC BRACHYTHERAPY LOADING ASSEMBLY

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit under § 119(e) of Provisional Patent Application Ser. No. 60/309,720, filed on Aug. 2, 2001 the contents of which are incorporated herein by reference, and is a continuation under 35 U.S.C. § 120 of pending U.S. patent application Ser. No. 10/161,239, filed on May 31, 2002, the contents of which is incorporated herein by reference.

BACKGROUND OF INVENTION

[0002] Brachytherapy is a form of cancer treatment in which a radioactive energy source is placed into or adjacent to a malignant tumor. Generally, brachytherapy can be divided into two categories: high dose rate (HDR); and low dose rate (LDR). In HDR brachytherapy, a radioactive energy source with high activity is placed into or adjacent to the malignant tumor for a predefined period of time. Conversely, LDR brachytherapy entails the placement of a low activity radioactive energy source into or adjacent to the malignant tumor for an indeterminate period of time.

[0003] In LDR brachytherapy, radioactive isotopes are used as the radioactive energy sources. Some of the more common radioactive isotopes used in LDR brachytherapy include Iodine-125, Palladium-103, Gold-198, Ytterbium-169, and Iridium-192. These isotopes are typically packaged in a housing constructed of a lightweight and durable material, such as titanium, and are commonly referred to as isotope seeds. The dimensions of the isotope seeds can be extremely variable both in diameter and in length. The radioactive isotopes commonly used in LDR brachytherapy are selected for their low energy and relatively short half-life. Low energy sources provide for a limited tissue penetration by the emitted radiation, so that the radiation's effects are limited to the tumor without substantially affecting adjacent normal tissue. A short half-life is advantageous in that the dose of radiation that is delivered depletes in a reasonably short period of time.

[0004] The area of therapeutic effect for Iodine-125 and Palladium-103 is limited to a sphere approximately 1 cm in diameter around the isotope seed. As a result, a three-dimensional array of isotope seeds is commonly used to treat a tumor. In LDR brachytherapy of prostate cancer, a multitude of isotope seeds is typically used. Since solid tumors, like those found in prostate cancer, are perceived to be diffuse, the entire organ is targeted for therapy.

[0005] In order to place isotope seeds into the aforementioned three-dimensional array, needles, using a two-dimensional grid pattern in conjunction with longitudinal spacing, can deliver isotope seeds. The two-dimensional grid is frequently defined by a needle guide, called a template. The template is provided with a plurality of holes that provide guidance for the longitudinal progression of the needles, thus insuring their desired two-dimensional position within the tumor. After the two-dimensional needle array is positioned within the tumor, the isotope seeds are deposited along the longitudinal axis of each needle.

[0006] Proper spacing of the isotope seeds along the longitudinal axis of the needle is accomplished through the use of biocompatible spacers further deposited between the isotope seeds. The use of spacers also serves to maintain the low energy effect on the prostate by maintaining a distance between the isotope seeds. The spacers and isotope seeds are alternately loaded into the needle prior to placement of the needle into the tumor. Upon placing the needle into the tumor, a cannula is engaged to maintain the position of the line of isotope seeds and spacers as the needle is withdrawn. This yields a line of isotope seeds in their proper longitudinal position. This process is repeated at the other two-dimensional grid coordinates, thus forming the desired three-dimensional array of isotope seeds.

[0007] An improved version of this procedure, as disclosed in U.S. Pat. No. 6,213,932, includes transparent plastic seed cartridges, detachably connected to the applicator, for holding a plurality of radioactive isotope seeds. This version enabled a surgeon to visually ascertain the number of spacers within a cartridge, thereby eliminating the guesswork previously involved in determining the number of remaining isotope seeds, greatly reducing the time required to load a needle.

[0008] A device that includes a cartridge having a plurality of individual isotope seeds, known as the Mick™ applicator system, registered to Mick Radio-Nuclear Instruments, Inc., is currently in widespread use. The cartridge retains a large number of individual isotope seeds that have been loaded therein at a separate facility. Additionally, isotope seeds can also be loaded into the cartridge at the hospital or at a nuclear pharmacy, thereby eliminating the time and cost requirements of loading individual isotope seeds in an operating room.

[0009] In the prior art, a seed-containing cartridge is attached to an applicator in a manner substantially similar to the way a magazine is attached to a firearm. The cartridge is spring-loaded to force one isotope seed at a time into a seed discharge chamber that further retains a single isotope seed for insertion into a needle. A special hollow needle is connected to the needle holder of a distal end of the applicator. A push rod is inserted into a distal end of the applicator and pushed directionally in a proximal-to-distal direction. The distal end of the push rod engages an isotope seed in the seed discharge chamber and drives the isotope seed into the hollow interior of the special needle and then out of the distal end of the needle into the prostate. The surgeon then extracts the needle to a predetermined distance, withdraws the plunger rod to a position on the proximal end of the seed discharge chamber so that an additional isotope seed can enter the chamber from the cartridge. Subsequent isotope seeds are then introduced into the needle, and then prostate, in an identical manner.

[0010] Although the Mick™ applicator system eliminates the risk of dropping individual isotope seeds in an operating room, it increases the amount of time required to implant a multitude of isotope seeds into the prostate because of the inability to inject more than one seed at a time. Further advances in this technique have additionally resulted in a reduction of the guesswork required by the surgical staff to determine the number of isotope seeds in a cartridge. However, these systems do not provide for either an identical loading system for spacers or for a system for visualizing the order of isotope seeds and spacers to be loaded into a needle.

[0011] Thus, there is a need for an improved applicator system that semi-automatically and sequentially loads radio-
active isotope seeds and biocompatible spacers and that enables a surgeon to visually ascertain the number and sequence of isotope seeds and spacers within a cartridge.

SUMMARY OF THE INVENTION

[0012] The present invention eliminates the above-mentioned needs for an improved version of the brachytherapy procedure for cancer treatment by providing a device and method for the semi-automatic and sequential loading of at least one isotope seed followed by at least one biocompatible spacer and that further enables a surgeon to visually ascertain the number and sequence of isotope seeds and spacers within a cartridge.

[0013] The present invention is directed to a semi-automatic loading assembly that includes a setting group, a loading group, a viewing member, and a seed receiving device holding group. The setting group further includes a handle, a push rod, and a stop block member. The handle is operatively engaged to the push rod, which is slidable within a push rod guide member. The push rod guide member passes through the stop block member, itself slidable mounted to a mounting plate. The stop block member can slidably select a number from the plurality of cartridges, and at least one first aligned unit of the first cartridge is deposited into a unit channel. The at least one first aligned unit of the first cartridge is driven along the unit channel to a first predetermined point. A second cartridge is then selected from the plurality of cartridges, with at least one second aligned unit of the second cartridge deposited into the unit channel. The at least one second aligned unit of the second cartridge is also driven along the unit channel to a second predetermined point by the push rod. The at least one first aligned unit of the first cartridge and the at least one second aligned unit of the second cartridge are subsequently inserted into a seed receiving device.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] FIG. 1 is an illustration of the preferred embodiment of the present invention.

[0017] FIG. 2 is an illustration of the loading block of the present invention illustrated in FIG. 1.

[0018] FIG. 3 is a cut-away illustration of the indexing member of the present invention illustrated in FIG. 1.

[0019] FIG. 4 is an illustration of the seed receiving device holder group of the present invention illustrated in FIG. 1.

[0020] FIG. 5 is an illustration of one aspect of, the operation of the preferred embodiment of the present invention.

[0021] FIG. 6 is an illustration of another aspect of the operation of the present invention of FIG. 5.

[0022] FIG. 7 is an illustration of still another aspect of the operation of the present invention of FIG. 5.

[0023] FIG. 8 is an illustration of yet another aspect of the operation of the present invention of FIG. 5.

[0024] FIG. 9 is an illustration of another aspect of the operation of the present invention of FIG. 5.

[0025] FIG. 10 is an illustration of still another aspect of the operation of the present invention of FIG. 5.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0026] Referring now to FIG. 1, a preferred embodiment of the present invention is illustrated as the semi-automatic brachytherapy loading assembly 10. The semi-automatic brachytherapy loading assembly 10 includes a setting group 20, a loading group 30, a viewing member 40, and a seed receiving device holding group 50. The setting group 20 further includes a handle 21, a push rod 22, and a stop block member 23. The handle 21 is operatively engaged to the push rod 22, which is slidable within a push rod guide member 24. The push rod guide member 24 is pass through the stop block member 23, itself slidably mounted to a mounting plate 60. Mounting plate 60 includes receiving tray 61 and stylet inserting block 62. The receiving tray 61 is adapted to collect isotope seeds and spacers that unintentionally fall out of the seed receiving device holding group 50. Stylet inserting block 62 is used for placing a stylet in a resting position. Additionally, the mounting plate 60 may itself be mounted to a series of receiving plates 63 to obtain an elevated position for mounting plate 60. The stop block member 23 slidably selects a number from a predefined series, indicating a number of radioactive isotope seeds or
biocompatible spacers. Furthermore, the stop block member 23 functions as the distal endpoint for the handle 21 that is in operative engagement with the push rod 22.

[0027] The loading group 30 of the assembly further includes a loading block 31 and an indexing member 32. The loading block 31 accommodates a slidable cartridge holder 33 that can hold a plurality of cartridges 34, including at least one seed cartridge and at least one spacer cartridge. Further, the loading block 31 includes an alignment visualizer 35 to provide visual confirmation of a selected cartridge. As illustrated in FIG. 2, slidable cartridge holder 33 secures cartridges 34 with cartridge clamps 35, which are tightened with screws 36 and retaining clips 37.

[0028] The indexing member 32 is spring-loaded and operatively engages the slidable cartridge holder 33 to select at least one cartridge from the plurality of cartridges 34a and 34b. As illustrated in FIG. 3, indexing member 32 includes a spring 38 and a dowel pin 32a. The indexing member 32 is slidable mounted on index support plate 39. Index support plate 39 has an integrated stop 39a to provide an end point to condense spring 38, thus forcing indexing member 32 to its resting position. The index support plate 39 is mounted to the underside of mounting plate 60, thereby permitting dowel pin 32a to engage the plurality of cartridges 34a and 34b to release an isotope seed or spacer, respectively.

[0029] As FIG. 1 illustrates, the viewing member 40 of the present invention further includes a body 41, a visualization plate 42, and a seed receiving device holder securement 43. The body 41 also includes a demarcation gauge 44 that permits identification of the number of isotope seeds and spacers to be loaded. The body 41 further accommodates the push rod guide member 24 and allows for the fixing of the visualization plate 42 by knobs 45, retaining clips 46, and lens clips 47. The visualization plate 42 allows for visualization of the demarcation gauge 44 while functioning as a radiation shield. Additionally, the seed receiving device holder securement 43 of the assembly accommodates the seed receiving device holder group 50.

[0030] As illustrated in FIG. 4, seed receiving device holder group 50 is composed of a seed receiving device holder flange 51, a seed receiving device holder hub 52, and a seed receiving device lock 53. The seed receiving device holder flange 51 is affixed to the seed receiving device holder securement 43 by screws 54 and dowel pin 55 and accommodates the seed receiving device holder hub 52 that further accommodates a seed receiving device. The seed receiving device is secured by the seed receiving device lock 53.

[0031] A preferred embodiment of the present invention semi-automatically and sequentially loads radioactive seed units and biocompatible spacer units into a brachytherapy device using the plurality of cartridges 34, with a plurality of aligned units contained therein, that is in operative engagement with the cartridge holder 33. A first cartridge is selected from the plurality of cartridges 34, and at least one unit of the first cartridge is deposited into a unit channel. The unit of the first cartridge is driven along the unit channel to a first predetermined point by the push rod 22, as visualized using demarcation gauge 44. A second cartridge is then selected from the plurality of cartridges 34, with at least one unit of the second cartridge also deposited into the unit channel. The unit of the second cartridge is also driven along the unit channel to a second predetermined point by the push rod 22, again as visualized using demarcation gauge 44. The unit of the first cartridge and the unit of the second cartridge are subsequently driven by the push rod 22 through seed receiving device holder hub 52 and inserted into a seed receiving device.

[0032] FIGS. 5-10 illustrate the operation of semi-automatic brachytherapy loading assembly 10. As shown in FIG. 5, a seed receiving device 80 is inserted into seed receiving device holder group 50 and secured by seed receiving device holder hub 52. As is further shown in FIG. 5, indexing member 32 is situated in a position, marked by indicator line 32a, which provides a user with a visual cue that neither an isotope seed nor a spacer has been selected for insertion.

[0033] FIG. 6 illustrates the process for selecting and positioning an isotope seed in accordance with the preferred embodiment of the present invention. As shown in FIG. 6, indexing member 32 is positioned to select an isotope seed. Once indexing member 32 is properly positioned, the user engages cartridge 34a for housing isotope seeds. By engaging cartridge 34a, isotope seed 70 is deposited in push rod guide member 24. Upon placement in push rod guide member 24, the user positions stop block member 23 out of the pathway of handle 21 so as to permit push rod 22 to travel a distance determined by the user and visualized at demarcation gauge 44. As illustrated in FIG. 7, once the user positions isotope seed 70 in the desired position, which can be viewed through demarcation gauge 44, the user then withdraws handle 21. The withdrawal of handle 21 causes push rod 22 to be withdrawn as well, thus leaving isotope seed 70 in the desired position. Further, as shown in FIG. 8, indexing member 32 can then be engaged to select a spacer from cartridge 34b. As with the selection of an isotope seed, once indexing member 32 is properly positioned, the user engages cartridge 34b for housing spacers. By engaging cartridge 34b, spacer 70 is deposited in push rod guide member 24. Upon placement in push rod guide member 24, again engages handle 21 so as to permit push rod 22 to travel a distance determined by the user and visualized at demarcation gauge 44. As illustrated in FIG. 9, once the user positions spacer 71 in the desired position in relation to isotope, seed 70, which can again be viewed through demarcation gauge 44, the user then withdraws handle 21. The withdrawal of handle 21 causes push rod 22 to be withdrawn as well, thus leaving isotope seed 70 and spacer 71 in their desired positions.

[0034] Once the desired number of isotope seeds and spacers are properly positioned, they can be inserted into seed receiving device assembly 80, as is illustrated in FIG. 10. In order to position isotope seed 70 and spacer 71 in seed receiving device 80, indexing member 32 is situated in the position marked by indicator line 32a, which provides a user with a visual cue that neither an isotope seed nor a spacer has been selected for insertion. The user then engages handle 21 so as to permit push rod 22 to travel a distance into seed receiving device 80. By doing so, isotope seed 70 and spacer 71 are placed in seed receiving device 80. Handle 21 is subsequently withdrawn, causing push rod 22 to be withdrawn as well, thus leaving isotope seed 70 and spacer 71 in their desired positions within seed receiving device 80 for insertion into a recipient.

[0035] Although only a few exemplary embodiments of the present invention have been described in detail above,
those skilled in the art will readily appreciate that numerous modifications are to the exemplary embodiments are possible without materially departing from the novel teachings and advantages of this invention. Accordingly, all such modifications are intended to be included within the scope of this invention as defined in the following numbered claims.

What is claimed is:

1. A brachytherapy loading assembly, constructed and arranged to help load seed receiving devices, comprising:
   a brachytherapy loading device having a seed receiving device fitting at a distal location where implantable seeds can be loaded into a seed receiving device positioned at the seed receiving device fitting, the brachytherapy loading device comprising a seed receiving conduit constructed to receive seeds and other implantation materials in a line, prior to loading into seed receiving device;
   the brachytherapy loading device also including a push rod that is slidable within the seed receiving conduit; and
   a stop block member constructed and arranged to selectively limit motion of the push rod within the conduit, so that when the stop block is in a first position, the push rod can extend far enough to push the seeds down the conduit but not far enough to reach the seed receiving device fitting, and when the stop block is in a second position, the stop block permits the push rod to extend to the seed receiving device fitting to eject seeds from the conduit to a seed receiving device mounted at the fitting.
2. The assembly of claim 1, wherein the brachytherapy loading device is mounted on a mounting plate so that it can be rested on a work surface during seed receiving device loading.
3. The assembly of claim 1, wherein the brachytherapy loading device comprises a viewing plate mounted over the conduit, located so that when the stop block member is in the first position, it permits the push rod to push the seeds to a location under the viewing plate.
4. The assembly of claim 3, wherein the viewing plate includes gradations which can assist in measuring the assembly of implantation materials prior to loading into a seed receiving device.
5. A brachytherapy loading assembly, comprising:
   a seed holder having a seed guide path in which a seed can be received and travel between a proximal and a distal direction;
   a loading block positioned in the guide path conduit;
   at least a first and a second cartridge mounted on the loading block, the loading block disposable between at least a first and a second position, wherein material from the first cartridge is in the guide path when the loading block is in the first position and material from the second cartridge is in the guide path when the loading block is in the second position.
6. The assembly of claim 5, wherein the first cartridge contains radioactive seeds and the second cartridge comprises spacing material for separating seeds.
7. The assembly of claim 6, wherein the assembly comprises a push rod within the seed guide path and when the loading block is in the first position, the push rod can push a radioactive seed out of the seed cartridge and when the loading block is in the second position, the push rod can push a spacer out of the non-radioactive spacer cartridge.
8. The assembly of claim 7, wherein the push rod is operatively engaged with a stop member and when the stop member is in a first short position, it restricts movement of the push rod to pushing material out of the cartridge, into the guide path and when the stop member is in a second long position, it permits the push rod to extend further down the guide path to push material in the guide path to the end of the guide path into a seed receiving device at the end of the guide path.
9. The assembly of claim 5, wherein the first cartridge is a Mick cartridge.
10. The assembly of claim 5, wherein the seed holder is mounted onto a mounting plate, constructed to rest on a table.
11. The assembly of claim 5, wherein the loading block is constructed to slide in a direction perpendicular to the guide path when moved between the first and second positions.
12. A brachytherapy loading assembly, comprising:
   a seed guide path having a groove at the distal end formed in a guide member thereof, sized to discharge brachytherapy seeds into a seed receiving device at the distal end thereof;
   a viewing member comprising a visualization plate over a distal section of the guide path groove, sufficiently transparent to permit viewing the seeds in the order in which they will be loaded out the distal end.
13. The assembly of claim 12, wherein the visualization plate has a demarcation gauge that permits identification and measurement of an alignment of seeds and spacers to be loaded.
14. The assembly of claim 12, wherein the visualization plate functions as a radiation shield.
15. The assembly of claim 12, wherein a loading block is slidingly mounted over the guide path, the loading block constructed to receive a cartridge thereon, and to selectively position material from the cartridge in the groove, as the block is moved back and forth with respect to the guide path.
16. The assembly of claim 15, wherein the loading block is constructed to retain a Mick cartridge.