A system for brachytherapy is provided. The system includes an implantation device having a spacer and a socket at opposing ends of the spacer. The device further includes a seed securely positioned within the socket. A plurality of spacers and seeds may be joined into an assembly. The device may be deployed at an implantation site by use of a delivery mechanism, such as needle. The presence of the spacers minimizes movement of the seeds subsequent to deployment, so as not to alter dose distribution for subsequent irradiation.
BRACHYThERAPY SYSTEMS AND METHODS

RELATED U.S. APPLICATION(S)

[0001] This application claims priority to U.S. Provisional Application Serial No. 60/290,108, filed May 10, 2001, which application is hereby incorporated herein by reference.

FIELD OF THE INVENTION

[0002] The present invention relates to implantable devices, and in particular, to implantable devices for radiation therapy.

[0003] 2. Background Art

[0004] Ionizing radiation is employed in the management of a wide variety of malignant tumors, providing a mechanism whereby the malignancy can be destroyed while the normal tissues are preserved. With preservation of normal tissues, normal function and normal appearance may also be preserved. Hence, ionizing radiation forms part of the treatment for over half of all patients with cancer. The overall effectiveness of radiation therapy, however, depends upon the balance between effective tumor control and morbidity due to the treatment. It is understood that the differential effects of ionizing radiation on tumors and normal tissues gives rise to a favorable therapeutic ratio for most patients. However, radiation can have destructive immediate and delayed effects on normal tissues. Techniques employed for radiation therapy significantly affect the incidence and severity of these destructive effects.

[0005] Because all types of ionizing radiation affect tissues via the same basic physical mechanisms, differences in spatial or temporal distributions are responsible for different effects observed with equal physical doses. The method for delivering radiation thus becomes highly significant. Treatment modalities for delivering therapeutic ionizing radiation include external beam radiation and direct placement of radioactive sources within tissues. This latter technique, termed brachytherapy, may permit delivery of ionizing radiation to a tumor in higher doses than those achievable with external beam radiation. Conventional external beam radiation treatments rely on multiple fractions of dose in order to ensure that the highest fraction of tumor cells are exposed at the most sensitive parts of the cell life cycle. Brachytherapy implants, such as brachytherapy seeds, on the other hand, can supply a continuous and highly localized radiation dose to the surrounding tissue. Because a delivered dose from a radiation source decreases proportionately to the square of the distance from that source, brachytherapy permits the delivery of very high radiation doses to those areas of a tumor in close proximity to the implant, with relative sparing of more distant tissues. With careful placement so that the radiation source is in proximity to the tumor and distant from normal tissue, effective therapy against the tumor may be combined with minimal collateral damage to normal tissues. A variety of radionuclides, including iodine-125, palladium-103, cesium-137, and iridium-192, may be used in the treatment of cancers involving such tissues as the breast, the prostate, the brain, along, the head and neck, the female reproductive tract, the musculoskeletal system and related soft tissues, and the eye.

Commonly, seeds are intended for permanent implantation. A description of certain types of seeds can be found in BH Heintz et al., “Comparison of I-125 sources used for permanent interstitial implants,” Medical Physics, Vol. 28, No. 4, p. 673 (April 2001), the contents of which are hereby incorporated by reference. Certain devices known in the prior art are intended for insertion directly into the tissues without employing a needle or other similar delivery device. An example of such a device may be found in the disclosure of U.S. Pat. No. 4,815,449. This patent provides, in certain embodiments, an implant of sufficient rigidity to be driven into a tumor without deflection, so that the implant may be used independently of a positioning or delivery device.

[0007] Alternatively, brachytherapy seeds may be positioned in the tissues to be treated by insertion through a delivery device, for instance, a needle. Using a delivery device may allow more precise positioning of seeds in areas requiring treatment. Brachytherapy seeds from various manufacturers may be made to the same set of specifications so that they are compatible with those delivery systems in common use. In those delivery systems, the seeds may be preloaded into needles or other delivery devices. The position of a plurality of seeds within the delivery device may be maintained by placing loose spacers between the seeds to establish and maintain a desired positioning. Once the seeds are positioned in the delivery device, insertion into the tissues takes place. To insert the seeds, the needle containing them must first be inserted to a preselected depth into the appropriate positioned in the patient’s tissues. An injection mechanism such as a mandrel may then be inserted into the needle with its distal end in contact with the seeds. The needle, thereafter, may be withdrawn over the mandrel, leaving the seeds and loose spacers resident in the preselected tissue area. Once positioned within the tissues using this method, the seeds and loose spacers are free to move from their original position, as there are no constraints on the position or orientation of the seeds. This can lead to the undesirable consequence that dose distribution within the tissue may be changed, for instance, movement of the seeds after deployment can change the area being irradiated, and can change the dose being delivered both to the preselected tumor regions and to the surrounding normal tissues.

[0008] There remains, therefore, a need for a system which can retain the brachytherapy seeds in position relative to one another prior to delivery, and which can retain the position of the brachytherapy seeds in relation to the tumor after the seeds are delivered into the tissues.

SUMMARY OF THE INVENTION

[0009] The present invention provides, in one embodiment, an implantable device for radiation therapy of pathological tissues. The device, in an embodiment, includes a substantially cylindrical member having opposing ends, a central section positioned between the ends, and a socket at each of the opposing ends. The device further includes a radionuclidic source partially positioned within one of the sockets, such that the blunt end on the radionuclidic source is exposed.

[0010] In another embodiment of the invention, an assembly of a plurality of cylindrical members, each having opposing ends, a central section positioned between the opposing end and a socket at each of the opposing ends. The
assembly further includes a radioactive source positioned between two cylindrical members, such that the radioactive source is partially retained within one socket of each cylindrical member, to permit joining of the cylindrical members in series along a common axis.

[0011] In a further embodiment, the invention provides a method for manufacturing a brachytherapy implant. The method includes providing a cylindrical member having opposing ends, a central section positioned between the opposing ends, and a socket at each of the opposing ends. Next, a radioactive source may be placed within a socket and subsequently secured therein. A second radioactive source may be placed in the opposing socket and subsequently secured therein.

[0012] A method of treating pathological tissues is also provided in accordance with an embodiment of the present invention. Initially, a site of pathological tissues is identified. Next, an implantable device is provided. The device, in one embodiment, includes at least one substantially cylindrical member having opposing ends, a central section between the opposing ends, a socket at each of the opposing ends, and at least one radioactive source positioned within one of the sockets. The device can thereafter be placed within a lumen of a delivery mechanism. Once the implantable device is placed within the lumen, the delivery mechanism can be inserted at the site having the pathological tissues to a depth which permits access to the pathological tissues. Subsequently, the implantable device can be delivered from the lumen of the delivery mechanism to the site of the pathological tissues.

BRIEF DESCRIPTIONS OF THE DRAWINGS

[0013] FIG. 1 illustrates an implantable device in accordance with one embodiment of the present invention.


[0015] FIGS. 3A-B illustrate another spacer embodiment for use with the device illustrated in FIG. 1.

[0016] FIG. 4 illustrates an assembly of implantable devices in accordance with an embodiment of the present invention.

[0017] FIGS. 5A-C illustrate a method for implanting the device, in accordance with one embodiment of the present invention.

DETAILED DESCRIPTION OF SPECIFIC EMBODIMENTS

[0018] FIG. 1 illustrates an implantable device 10 for radiation therapy of pathological tissues, for example, a tumor, through the use of a delivery device, such as a needle. As shown FIG. 1, the device 10 includes, in accordance with one embodiment of the present invention, a substantially cylindrical spacer 14 and radioactive sources, such as seeds 12 and 18, positioned at opposing ends of the spacer 14.

[0019] Looking now at FIGS. 2A-B, the spacer 14, in an embodiment, includes a substantially solid central section 22 and opposing sockets 24 and 26 positioned at each end of the central section 22. The opposing sockets 24 and 26, are adapted so that each can receive and retain a portion of a radioactive seed 12 or 18, or a space-occupying socket filler (not shown). In this manner sockets 24 and 26 may be provided with an inner diameter D which can securely receive a seed 12 or 18 therein. It should be noted that, although illustrated in FIGS. 2B as circular, each socket may be provided with a diameter D and a circumferential profile of any geometrical pattern, as radioactive seeds for brachytherapy may come in various dimensions and configurations, so long as the seed can be securely positioned within the socket. If desired, the opposing sockets 24 and 26 may be provided with similar inner diameters and/or circumferential profiles, or with different inner diameters and/or circumferential profiles.

[0020] In accordance with one embodiment of the present invention, the spacer 14 can include an inner diameter D of about 0.8 millimeters (mm), suitable for accommodating a brachytherapy seed, and an outer diameter D' of about 1.0 mm, suitable for unobstructed passage through an interior channel (i.e., lumen) of a needle (FIGS. 5A-C) or other delivery devices employed in the implantation of brachytherapy seeds into a patient. For example, an 18 gauge needle, suitable for implant delivery, is understood to have an interior channel with a diameter of about 1.05 mm, which diameter should provide sufficient clearance for the spacer 14 to pass therethrough. The spacer 14 can also include a central section 22 that is approximately 5.5 mm in length, and opposing sockets 24 and 26 that are each approximately 2 mm in length to provide a spacer 14 that is approximately 9.5 mm or slightly longer in length. It should be appreciated that the inner diameter D, the outer diameter D', the central section 22 and the sockets 24 and 26 can be manufactured with different dimensions to accommodate the type of treatment to be performed.

[0021] The spacer 14 of the present invention, as it is designed for delivery and placement within tissues through a delivery device, may be made from a flexible material. In one embodiment of the present invention, the spacer 14 may be made from a bioreabsorbable polymer, such as poly(L-lactide), poly(DL-lactide), polyglycolide, or any other bioreabsorbable polymer known to those skilled in the art. In certain embodiments, the polymeric formulation may be chosen, so that the absorption thereof would be minimal over a certain period, for example, from about 60 to about 120 days, with substantially complete absorption thereof in about a year.

[0022] The spacer 14 may be fabricated, in accordance with an embodiment, by injection molding or by similar processes. Preferably, spacer 14 may be manufactured as a single piece, such that the central member 22 and the opposing sockets 24 and 26 are integral with one another.

[0023] In an alternative embodiment, referring now to FIGS. 3A-B, the spacer 14 may be assembled from two different pieces, a tubular member 32 and a solid plug 34. As illustrated therein, solid plug 34 may be inserted towards a center of a relatively longer tubular member 32, such that the difference in length between the plug 34 and the tubular member 32 defines the sockets 36 and 38 at each of the opposing ends of the tubular member 32.

[0024] The spacer 14, fabricated in the manner illustrated in FIGS. 3A-B, may have its components, such as the tubular member 32, manufactured by an extrusion method, dip-casting, or other processes familiar to those skilled in the art. In the dip-casting method, a metal rod may be dipped
into a viscous solution to coat the surface of the rod. Subsequently, after drying, the coating on the metallic rod can be pulled off to provide tubular member 32. The solid plug 34 can thereafter be inserted within the tubular member 32 and affixed therein by the use of, for instance, a friction-fit, biocompatible cement, biodegradable cement, or by any other affixation method known in the art. Of course, the solid plug 34 need not be affixed within the tubular member 32 and its position may be maintained by placement of the brachytherapy seeds into the opposing sockets of tubular member 32.

[0025] With reference now to the radioactive seeds 12 and 18, as shown in FIG. 1, each of seeds 12 and 18 is substantially elongated and includes a proximal end 20 and a distal end 21. The proximal end 20 is typically received within the sockets of device 10. The exposed distal end 21, on the other hand, may be rounded or blunted, so that trauma to surrounding tissues can be minimized during and subsequent to the implantation of the device 10. In an embodiment of the invention, both the distal end 20 and proximal end 21 can be rounded or blunted, so that regardless of which end is within a socket of device 10, the remaining exposed portion of the seed 12 includes a blunt end.

[0026] The seeds for use in connection with the device 10 of the present invention may be manufactured, in one embodiment, from a variety of radioisotopes, including iodine-125, palladium-103, cesium-137, and iridium-192. The seeds for use with the device 10 may also be obtained commercially, for instance, seed model 3500 manufactured by Implant Sciences Corporation of Wakefield, Mass., or may be any other seed model familiar to skilled artisans. Although illustrated in FIG. 1 as two similarly dimensioned seeds 12 and 18, it should be understood that various dimensions and configurations of the seeds may be employed in accordance with the therapeutic demands of a particular clinical situation. Moreover, seeds of differing sizes may be employed for use within one implantable device 10.

[0027] The seeds 12 and 18, in an embodiment, may be secured to the spacer 14 by means of a friction-fit (i.e., press-fit), a biodegradable cement, a biocompatible cement, or by any other affixation method known to those skilled in the art.

[0028] Referring now to FIG. 4, the device 10 may be joined with another to provide an assembly 40 of spacers 42 and seeds 44. As illustrated, additional spacers 42 may be added to the assembly 40 by positioning an existing exposed distal end of the seed 44 within a socket of a new spacer 40. Depending on the situation and the treatment required, the assembly 40 may include a seed 44 at each end of the assembly, one seed at an end of the assembly with the other end empty leaving an exposed socket, or no seed at either end of the assembly. Affixation of the seeds 44 to the spacers 42 may be accomplished by employing the means provided above.

[0029] To treat pathological tissues, looking now at FIGS. 5A-C, an assembly 50 of spacers 51 and seeds 52 may be fabricated and positioned within a lumen 53 of a delivery device, such as a needle 54. The needle 54, subsequently, can be placed at a site selected for implantation and inserted to a preselected depth, so as to permit the needle to access the pathological tissues. An injection mechanism, such as a mandrel 55, can then be inserted into the needle 54 until its distal end contacts the assembly 50. The needle 54 may, thereafter, be withdrawn over the mandrel 55, leaving the assembly 50 at the site of implantation. The presence of the spacers 51 prevents the seeds 52 from substantially moving away from the initial site of implantation, so as not to alter the dose distribution within the tissue for subsequent irradiation.

[0030] Alternatively, the site selected for implantation can initially be surgically exposed. Thereafter, the assembly 50 can be placed within the exposed site. Once the assembly 50 has been securely positioned within the site, the site may be closed by suturing to retain the assembly 50 therein.

[0031] It should be understood that although an assembly is disclosed in connection with the treatment of pathological tissues, an implantation device having one spacer 51 and one or two radioactive seeds 52 may be used.

[0032] While the invention has been described in connection with the specific embodiments thereof, it will be understood that it is capable of further modification. Furthermore, this application is intended to cover any variations, uses, or adaptations of the invention, including such departures from the present disclosure as come within known or customary practice in the art to which the invention pertains, and as fall within the scope of the appended claims.

What is claimed is:

1. An implantable device for radiation therapy comprising:
   a substantially cylindrical member having opposing ends, a central section positioned between the opposing ends, and a socket at each of the opposing ends; and a radioactive source having a blunt end and being partially positioned within one of the sockets, such that the blunt end on the radioactive source is exposed.

2. A device as set forth in claim 1, wherein the central section is integral with the sockets at each of the opposing ends of the cylindrical member.

3. A device as set forth in claim 1, wherein the central section includes a plug distinct from and relatively shorter than the cylindrical member, such that difference in length between the plug and the cylindrical member defines the socket at each of the opposing ends of the cylindrical member.

4. A device as set forth in claim 1, wherein each of the sockets includes an inner diameter sufficiently sized to securely retain the radioactive source therein.

5. A device as set forth in claim 1, wherein each of the sockets includes a depth sufficient to retain a portion of the radioactive source, so as to minimize movement of the radioactive source after implantation.

6. A device as set forth in claim 1, wherein the cylindrical member is made from a flexible material.

7. A device as set forth in claim 1, wherein the cylindrical member is made from a bioresorbable material.

8. A device as set forth in claim 7, wherein the bioresorbable material includes a formulation which permits relatively minimal resorption over a defined period with subsequent substantially complete resorption thereafter.

9. A device as set forth in claim 7, wherein the bioresorbable material includes poly-(L-lactide), poly-(DL-lactide), polyglycolic acid, or a combination thereof.
10. A device as set forth in claim 1, wherein the radioactive source is a substantially elongated segment.

11. A device as set forth in claim 10, wherein the radioactive source includes one of iodine-125, palladium-103, cesium-137, and iridium-192.

12. An assembly for radiation therapy comprising:
   a plurality of cylindrical members, each having opposing ends, a central section positioned between the opposing ends, and a socket at each of the opposing ends;
   a radioactive source positioned between two cylindrical members, such that the radioactive source is partially retained within one socket of each cylindrical member, to permit joining of the cylindrical members in series along a common axis.

13. An assembly as set forth in claim 12, further including a radioactive source partially positioned within a distalmost socket of a distalmost cylindrical member in the series.

14. An assembly as set forth in claim 13, wherein the radioactive source positioned within the distalmost socket includes an exposed blunt end.

15. A method for manufacturing a brachytherapy implant, the method comprising:
   providing a cylindrical member having opposing ends, a central section positioned between the opposing ends, and a socket at each of the opposing ends;
   placing a radioactive source within a socket; and
   securing the radioactive source within the socket.

16. A method as set forth in claim 15 further comprising:
   placing a second radioactive source with the opposing socket; and
   securing the second radioactive source within the opposing socket.

17. A method for manufacturing a brachytherapy implant, the method comprising:
   providing a tubular member having opposing ends;
   placing within the member a plug having a length relatively shorter than that of the member, such that the difference between the plug and the tubular member defines a socket at each of the opposing ends of the tubular member;
   positioning a radioactive source within a socket; and
   securing the radioactive source within the socket.

18. A method as set forth in claim 17 further comprising:
   positioning a second radioactive source with the opposing socket; and
   securing the second radioactive source within the opposing socket.

19. A method as set forth in claim 17, wherein the step of placing includes securing the plug to the tubular member.

20. A method for treating pathological tissues, the method comprising:
   identifying a site having pathological tissues;
   providing an implantable device comprising at least one substantially cylindrical member having opposing ends, a central section positioned between the opposing ends, a socket at each of the opposing ends, and at least one radioactive source positioned within one of the sockets;
   positioning the implantable device within a lumen of delivery mechanism;
   inserting the delivery mechanism at the site having the pathological tissues to a depth which permits access to the pathological tissues; and
   delivering the implantable device from the lumen of the delivery mechanism to the site of pathological tissues.

21. A method for treating pathological tissues, the method comprising:
   providing an implantable device comprising at least one substantially cylindrical member having opposing ends, a central section positioned between the opposing ends, a socket at each of the opposing ends, and at least one radioactive source positioned within one of the sockets;
   surgically exposing a site having pathological tissues;
   positioning the implantable device within the exposed site; and
   closing the exposed site to retain the implantable device therein.

* * * * *