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Expanding multi-lumen applicator operating within a balloon

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Partridge et al.

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(54) **EXPANDING MULTI-LUMEN APPLICATOR OPERATING WITHIN A BALLOON**

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A61N 5/00 (2006.01)

(52) **U.S. Cl.** **600/6**; 600/3

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See application file for complete search history.

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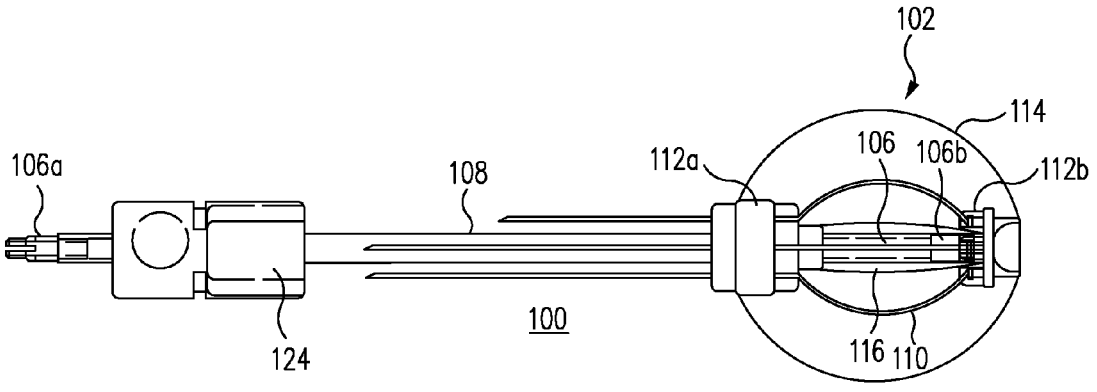
(57) **ABSTRACT**

A brachytherapy apparatus includes a distal support member and a proximal support member movable relative to the distal support member. The apparatus includes a plurality of elongate treatment members having distal first locations coupled to the distal support member, proximal second locations coupled to the proximal support member, and pathways between the proximal second locations and the distal first locations adapted to receive one or more radiation sources. Each of the treatment members is movable between a generally straight configuration and a curvilinear configuration. An expandable member encloses and provides a spatial volume for the plurality of the treatment members and is adjustable between a contracted configuration and an expanded configuration.

22 Claims, 4 Drawing Sheets



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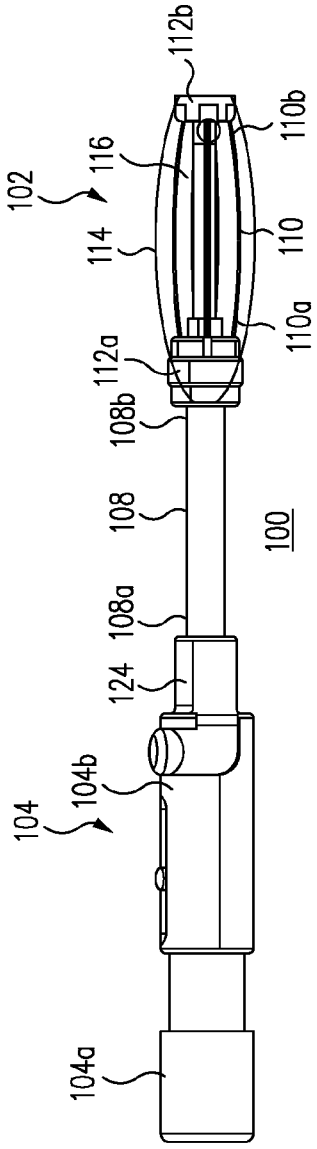
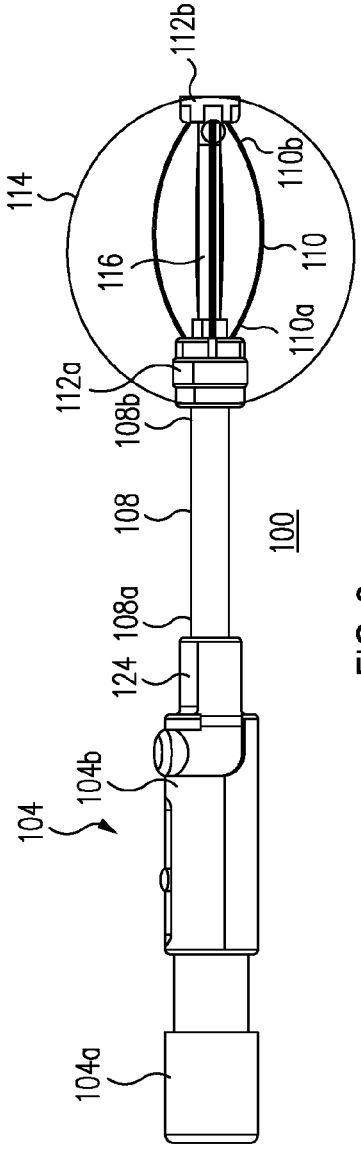

112b
110b
116
102
114
110
110a
112a
108b
108
100
108a
124
104b
104
104a

FIG. 1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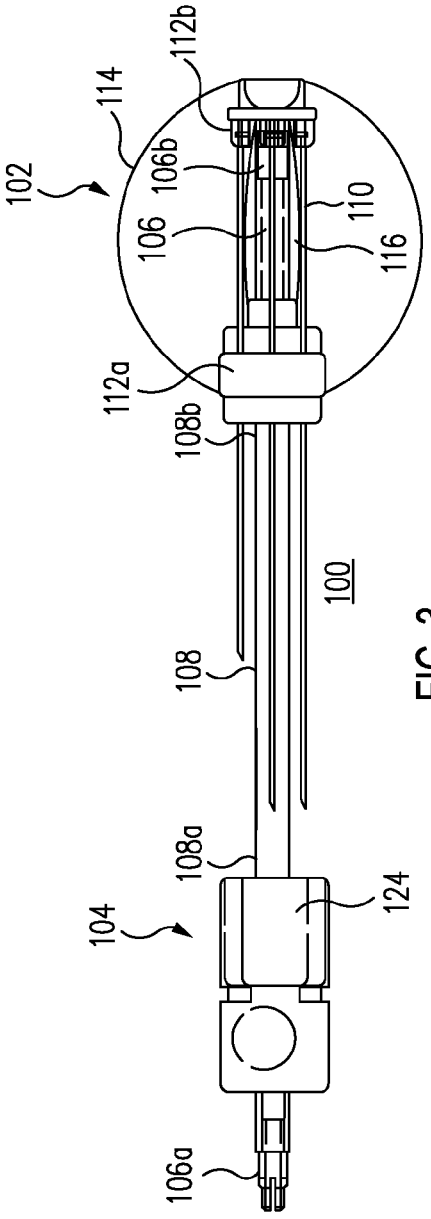
104a

FIG. 2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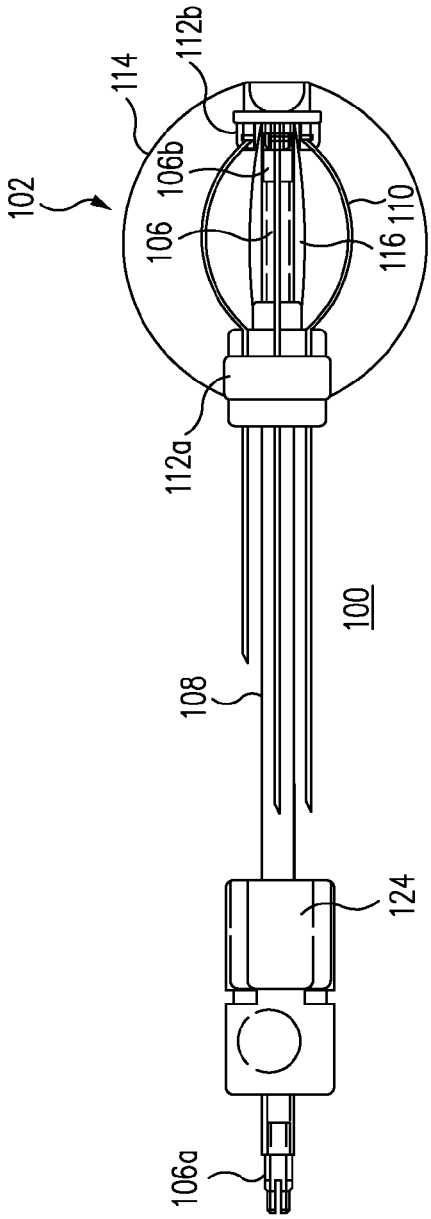
114
112b
106b
106
110
116
112a
108b
100
108
108a
104
124
106a

FIG. 3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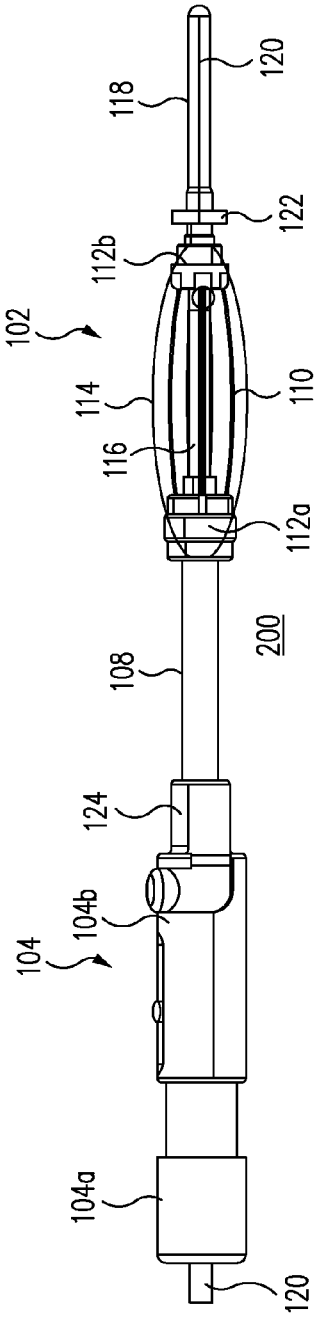
114
112b
106b
106
110
116
112a
100
108
124
106a

FIG. 4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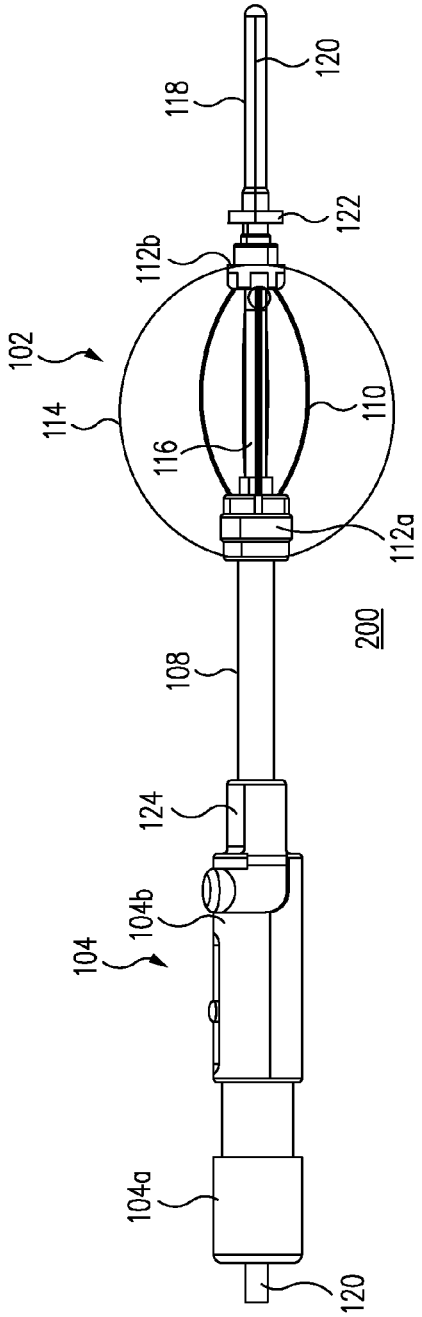
122
112b
102
114
110
116
112a
200
108
124
104b
104
104a
120

FIG. 5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112b
102
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104b
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104a
120

FIG. 6

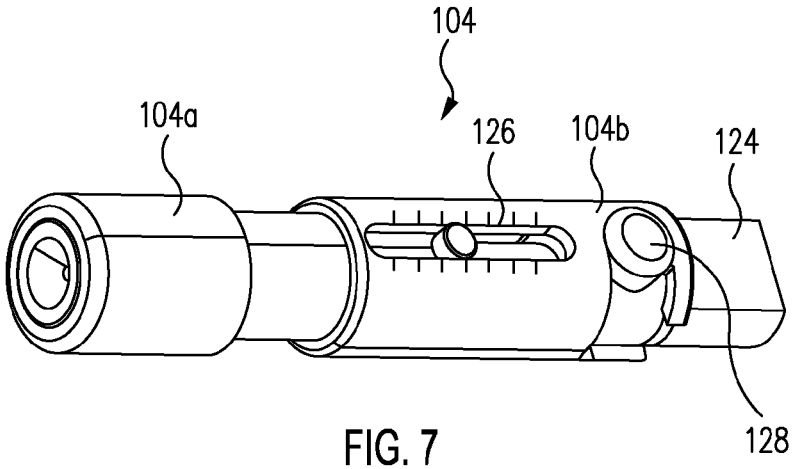

FIG. 7

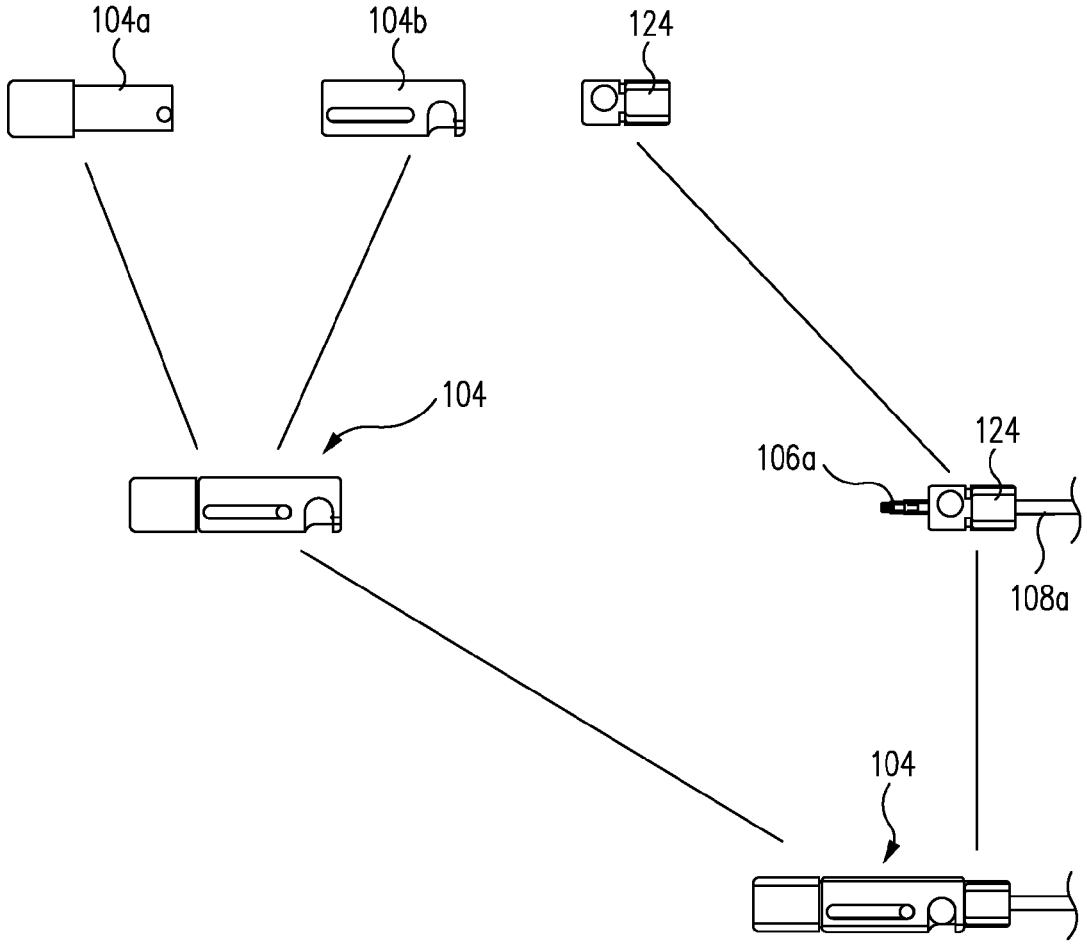

FIG. 8

EXPANDING MULTI-LUMEN APPLICATOR OPERATING WITHIN A BALLOON

BACKGROUND

This invention relates in general to radiation therapy and in particular to apparatuses and methods for providing brachytherapy to a human or other mammalian body.

Brachytherapy is a type of radiation therapy that involves placing radioactive materials directly into or immediately adjacent to a target, which may be a tumor or tissue surrounding a cavity that contains cancerous cells. Brachytherapy has been used in treatment of a large number of malignancies including cancer in the uterus, uterine cervix, vagina, prostate, rectum, lung, and breast. One major advantage of brachytherapy is that very high doses of radiation can be delivered locally to the target in a relatively short time, while relatively low doses are delivered in the surrounding tissue. This adheres to the premise in radiation therapy that tumoricidal doses must be deposited in the tumor while sparing as much normal tissue and/or critical organs as possible. The use of brachytherapy in cancer treatment is increasing, partly due to the increasing desire for organ preservation and acceptable cosmetic results.

Significant achievements in brachytherapy have been made, however challenges remain. For example, conventional brachytherapy techniques generally lack the ability to adjust the pathways of radioactive materials in a target site, resulting in less desirable treatment dosimetry. Another issue with conventional brachytherapy techniques is that they require structures often made of metal or plastic for passing radioactive materials right next to the body tissue. The bare metal structures may cause unpleasant effect on patients, prohibits CT/MR scanning of the anatomy to be treated because of excessive artifacts, and create non-uniform dose distributions or overexposure of doses to adjacent healthy tissue.

SUMMARY

The present invention provides brachytherapy apparatuses and methods that are particularly useful in treatment of diseases in the uterus, uterine cervix, vagina, endometrial, rectum, breast, or other body portions. In one embodiment, a brachytherapy apparatus includes a distal support member and a proximal support member movable relative to the distal support member. The apparatus includes a plurality of elongate treatment members having distal ends coupled to the distal support member, proximal ends coupled to the proximal support member, and pathways between the proximal ends and the distal ends adapted to receive one or more radiation sources. Each of the treatment members is movable between a generally straight configuration and a curvilinear configuration. An expandable member encloses the plurality of the treatment members and is adjustable between a contracted configuration and an expanded configuration.

The expandable member may be configured to provide various expanded configurations. In some embodiments, the expanded configuration may be in a generally cylindrical shape. In some embodiments, the expanded configuration may be in a generally spherical shape.

The expandable member may be constructed with a material comprising a polymer selected from the group consisting of polyurethane (PUR), polyvinyl chloride (PVC), low-density polyethylene (LDPE), polyamide, and polyethylene terephthalate (PET). In a preferred embodiment, the expandable member in the contracted configuration has a thickness ranging from 15 to 30 micrometers.

The apparatus may include 2-20 elongate treatment members. Collectively, the treatment members in the curvilinear configuration may provide a generally "egg beater" or "rugby" configuration.

The apparatus may include a first elongate body and a second elongate body that are movable relative to each other. The second elongate body may be slidably or rotatably disposed around the first elongate body and axially movable relative to the first elongate body. The distal and proximal support members may be coupled to the distal portions of the first and second elongate bodies respectively, and move with the first and second elongate bodies.

The apparatus may include a handle portion adapted to operate the treatment members between a generally linear configuration and a curvilinear configuration. The handle portion may be detachable from the apparatus to reduce the profile of the apparatus, or re-attachable to the apparatus for readjustment. The handle may include a scale with reference that indicates the degree of the movement of the treatment members. The handle may further include a lock and release mechanism to limit the movement of the treatment members.

In some embodiments, the apparatus may include a seal member to seal the moving parts from the inflation fluid used for expanding the expandable member.

In some embodiments, the apparatus may further include an extension member outside the expandable member and having a pathway adapted to receive one or more radiation sources. The extension member may be a cervical sleeve configured to be deployed in the uterine cervix. The extension member may also be an intrauterine tandem having a curvature configured to be deployed in the uterus.

In a preferred embodiment, a brachytherapy apparatus includes a first elongate body, a second elongate body, and a plurality of elongate treatment members disposed near the distal portions of the first and second elongate bodies. The second elongate body may be slidably or rotatably disposed around the first elongate body and axially movable relative to the first elongate body. The treatment members may be movable between a generally straight configuration and a curvilinear configuration, and have pathways adapted to receive one or more radiation sources. The plurality of the treatment members are enclosed within an expandable member which may be adjustable between a contracted configuration and an expanded configuration. The apparatus may further include an elongate extension member disposed outside the expandable member and coupled to the distal portion of the first elongate body. The extension member may have a pathway adapted to receive one or more radiation sources. The extension member may be a cervical sleeve to fit in the uterine cervix for treatment of cervical diseases, or a curved intrauterine tandem to be positioned in the uterus for treatment of endometrial diseases.

In a further preferred embodiment, a brachytherapy apparatus includes one or more treatment members each having a distal end coupled to a distal support member, a proximal end coupled to a proximal support member, and a pathway between the distal end and the proximal end adapted to receive one or more radiation sources. An expandable member encloses the one or more treatment members, and changeable between a contracted configuration and an expanded configuration. The expandable member in the contracted configuration may have a thickness ranging from 15 to 30 micrometers. The expandable member is preferably constructed with an elastic polymeric material. The one or more

treatment members are preferably movable between a generally straight configuration and curvilinear configuration.

BRIEF DESCRIPTION OF THE DRAWINGS

These and various other features and advantages will become better understood upon reading of the following detailed description in conjunction with the accompanying drawings and the appended claims provided below, where:

FIG. **1** is a side view of an exemplary brachytherapy apparatus showing a plurality of treatment members in a generally straight configuration and an expandable member in a contracted configuration;

FIG. **2** is a side view of an exemplary brachytherapy apparatus showing a plurality of treatment members in a curvilinear configuration and an expandable member in an expanded configuration;

FIG. **3** is a side view of an exemplary brachytherapy apparatus showing a plurality of treatment members in a generally straight configuration and an expandable member in an expanded configuration;

FIG. **4** is a side view of an exemplary brachytherapy apparatus showing a plurality of treatment members in a curvilinear configuration and an expandable member in an expanded configuration;

FIG. **5** is a side view of an exemplary brachytherapy apparatus showing a plurality of treatment members enclosed in an expandable member in a contracted configuration, and an extension member;

FIG. **6** is a side view of an exemplary brachytherapy apparatus showing a plurality of treatment members enclosed in an expandable member in an expanded configuration, and an extension member;

FIG. **7** is a perspective view of an exemplary handle; and

FIG. **8** is an exploded view of the handle illustrated in FIG. **7**.

DETAILED DESCRIPTION OF VARIOUS EMBODIMENTS

Various embodiments of apparatuses and methods for radiation therapy and imaging are described. It is to be understood that the invention is not limited to the particular embodiments described as such may, of course, vary. An aspect described in conjunction with a particular embodiment is not necessarily limited to that embodiment and can be practiced in any other embodiments. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting since the scope of the invention will be limited only by the appended claims, along with the full scope of equivalents to which such claims are entitled.

In addition, various embodiments are described with reference to the figures. It should be noted that the figures are not drawn to scale, and are only intended to facilitate the description of specific embodiments. They are not intended as an exhaustive description or as a limitation on the scope of the invention.

All technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs, unless defined otherwise. As used in the description and appended claims, the singular forms of "a," "an," and "the" include plural references unless the context clearly dictates otherwise. Thus, for example, reference to "a radiation source" includes one or more radiation sources, and reference to "the treatment member" includes one or more treatment members of the form or configuration described herein.

The invention provides a brachytherapy apparatus that can be inserted into a living body and be held in place for delivery of radiation to a target. The apparatus is provided in a form that is as small as possible to aid insertion into the living body. The apparatus has a mechanism to expand once in place in the living body to localize the apparatus, or to provide a space for adjusting treatment members having channels or pathways that are adapted to receive radiation sources. Once in place, the apparatus is connected to a system that provides radiation sources.

As used herein "treatment target" or "target" refers to any portion of a human or mammalian body that is identified to benefit from radiation therapy. The treatment target may include a tumor itself, or tissue surrounding or adjacent to a cavity that contains cancerous cells. The cavity may be a natural void in a living body such as uterus, vagina, uterine cervix, and rectum etc., or created by removing a tumor from the body such as a lumpectomy cavity in the breast.

As used herein "radiation source" refers to any therapeutic element that is operable to deliver a dose of radiation. The radiation source may be a high dose rate radioactive material, medium dose rate radioactive material, low dose rate radioactive material, or any combination. By way of example, suitable radiation sources include Ir-192, Co-60, Cs-131, I-125, Pd-103, Au-198, W-187, Yb-169, Gd-153, Sm-145, Cs-137, Cd-109, Zn-65, Co-58, Co-57, Co-56 and so on. The radiation source maybe in the form of solid or liquid. For example, the radiation source may be contained in a solution, or suspended in a suspension as small particles of solid radionuclides. In some embodiments, the radiation source may be in any suitable solid forms such as cylinders, capsules, plates, lines, and points, etc. The radiation source can be either preloaded into the apparatus at the time of manufacturing, or loaded into the apparatus after it has been deployed in the living body using e.g. an elongate wire carrying the radiation source.

As used herein a "proximal" end or portion of a member, body, or any component refers to the end or portion that is closer to a user along a longitudinal axis of the member, body or component, while a "distal" end or portion refers to the end or portion that is farther to the user. A proximal or distal end includes an extremity and a portion proximal to the extremity.

FIGS. **1-4** illustrate exemplary brachytherapy apparatuses **100** in accordance with some embodiments. In general, the brachytherapy apparatus **100** includes an applicator or treatment delivery portion **102**, and a handle portion **104** for operating the treatment delivery portion **102**. The treatment delivery portion **102** may be deployed in a target site within a patient's body, e.g., in a void such as vagina, uterus, uterine cervix, rectum, or a lumpectomy cavity in a breast. The handle portion **104** extends from the treatment delivery portion **102** and protrudes outside of the patient's body. The handle portion **104** may be detached from the treatment delivery portion **102** after the apparatus **100** is properly deployed at the target site. The handle portion **104** may be reattached to the treatment delivery portion **102** for readjustment of the apparatus **100** during treatment, or for removing the apparatus **100** out of the patient's body after treatment. The configuration of the treatment delivery portion **102** may be changeable or adjustable between a contracted or collapsed configuration (FIG. **1**) and an expanded configuration (FIGS. **2**, **3**, and **4**). A contracted configuration facilitates passage of the apparatus into the target site. An expanded configuration facilitates localizing the apparatus in the target site, providing space for radiation source pathway adjustment, or providing

spacing between the radiation source and adjacent critical organs or healthy tissue to prevent overexposure of radiation doses.

The apparatus **100** may include an inner tube or a first elongate body **106** having a proximal portion **106***a* and a distal portion **106***b* (FIG. **3** or **4**), and an outer shaft or a second elongate body **108** having a proximal portion **108***a* and a distal portion **108***b*. The second elongate body **108** may be slidably or rotatably disposed around the first elongate body **106** and axially movable relative to the first elongate body **106**. The apparatus **100** includes one or more elongate catheters or treatment members **110** adapted to receive one or more radiation sources. The treatment members **110** include proximal ends **110***a*, distal ends **110***b*, and channels or pathways between the proximal and distal ends. The proximal ends **110***a* of the treatment members **110** may be coupled to the distal portion **108***b* of the second elongate body **108**. The distal ends **110***b* of the treatment members **110** may be coupled to the distal portion **106***b* of the first elongate body **106**. One or more support members may be used to secure the treatment members **110**. For example, a proximal support member **112***a* may be coupled to the distal portion **108***b* of the second elongate body **108** for securing the proximal ends **110***a* of the treatment members **110**. A distal support member **112***b* may be coupled to the distal portion **106***b* of the first elongate body **106** for securing the distal ends **110***b* of the treatment members **110**. The proximal or distal support members **112***a*, **112***b* may have a series of openings adapted to receive or secure the distal or proximal ends **110***a*, **110***b* of the treatment members **110**. The openings may be spaced apart or evenly spaced apart along a circular path. The distal support member **112***b* may include a plurality of pivot joints **113** to which the plurality of treatment members **110** are coupled to aid spreading of the treatment members **110** to desired curvilinear configuration.

The treatment members **110** may be flexible or changeable between a generally straight configuration and a curvilinear configuration. The change between a straight configuration and a curvilinear configuration can be caused by changing the linear distance between the proximal ends **110***a* and the distal ends **110***b* of the treatment members **110**. For example, moving the proximal and/or distal support members **112***a*, **112***b* can bring the proximal ends **110***a* and distal ends **110***b* of the treatment members **110** closer or take the two ends farther away, thereby bowing or straightening the treatment members **110**. The movement between the proximal and distal support members **112***a*, **112***b* may be provided by displacing the first and second elongate bodies **106**, **108**. For example, by displacing the second elongate body **108** in a distal direction, or by displacing the first elongate body **106** in a proximal direction, the proximal and distal ends **110***a*, **110***b* of the treatment members **110** may be brought closer to each other, thereby bowing the treatment members **110** from a generally straight configuration. Conversely, the treatment members **110** may be straightened from a curvilinear configuration by displacing the second elongate body **108** in a proximal direction, or by displacing the first elongate body **106** in a distal direction. Collectively, the curvilinear treatment members may form an "egg beater" or "rugby" configuration. The size of the formed "egg beater" or "rugby" may be predetermined based on the size or shape of the target site, and can be controlled by the relative movement between the first and second elongate bodies **106**, **108**.

The channels or pathways of the treatment members **110** are adapted to receive one or more radiation sources. By changing the configuration of the treatment members **110** between a generally straight and a curvilinear configuration, the pathways of the radiation source or sources within the target site can be adjusted to provide a controlled dosimetry. The number of the treatment members **110** may be chosen depending on the location or size of the target site and may vary widely e.g. ranging from 1 to 20. In some embodiments, 2-20 treatment members **110** are provided. In some embodiments, 2-12 or 4-8 treatment members **110** are provided. The plurality of treatment members and their curvilinear configurations can advantageously aid in delivery of radiation to a target in a three-dimensional way.

In some embodiments, the proximal ends **110***a* of the treatment members **110** may be extended through the proximal support member **112***a* and outside of the living body (FIGS. **3** and **4**) to be connected to e.g. an after-loader. The treatment members **110** may be continuous members, or be formed from multiple sections connected to each other by suitable means such as bonding or lapping etc.

Expandable member **114** encloses the treatment members **110** and may be bonded or otherwise affixed to the proximal and distal support member **112***a*, **112***b*. Expandable member **114** may provide a continuous enclosure for the treatment members **110**. The expandable member **114** may be changeable or adjustable between a contracted configuration and an expanded configuration, and as a result, the spatial volume defined by the expandable member **114** is also adjustable. For instance, the expandable member **114** may be in a contracted configuration to facilitate insertion of the apparatus **100** into a target site in a patient's body. Once the apparatus **100** is in place, the expandable member **114** may be expanded to an expanded configuration by e.g. introducing an inflation fluid into the enclosure defined the expandable member **114**. The expansion of the expandable member **114** provides a geometry that retains the apparatus **100** in the target site during the treatment session. The expansion of the expandable member **114** also provides room for the treatment members **110** to change from a generally straight configuration to a curvilinear configuration for adjusting the pathways of the radiation sources. The expansion may further provide spacing between the radiation sources and adjacent critical organs or healthy tissues. In some embodiments, the expandable member **114** may be made sufficiently firm to force the target tissue to take the configuration of the expandable member **114** such that the adjacent or surrounding tissue receives a uniform radiation dose.

The expandable member **114** can be configured to form any suitable expanded configurations based on the form or size of the target site in which the apparatus would be deployed. By way of example, for treatment of vaginal diseases, the expandable member **114** can be configured to form an expanded configuration in a generally cylindrical shape or other suitable shapes. For treatment of endometrial diseases, the expandable member **114** can be configured to form an expanded configuration in a generally spherical shape that is suitable to be retained in the uterus. In general, the expandable member **114** can be configured to form an expanded configuration in any regular or irregular shape for deploying in any part of the living body including e.g. lumpectomy cavities in the breast which often have an irregular shape. The size of the expanded configuration can also be predetermined to fit in the target site. In general, the expanded configuration of the expandable member **114** may have a transverse dimension ranging from 1 to 15 cm, or from 2 to 10 cm. By way of example, for treatment of vagina or other diseases, an expanded cylindrical configuration may have a diameter ranging from 2 to 10 cm, and a length ranging from 4 to 10 cm.

For treatment of endometrial or other diseases, an expanded spherical configuration may have a diameter ranging from to 2 to 10 cm.

Various expandable members may be used including inflatable balloons. Inflatable balloons are distensible devices which may be, but not necessarily, constructed with elastic materials. The expandable members **114** may be constructed with materials that are generally impermeable to body fluids such as blood and the like, or impermeable to radiation materials. An impermeable expandable member may be useful in preventing radiation materials or inflation fluid from leaking from the apparatus or preventing contamination of the apparatus or tissue of the patient.

In some preferred embodiments, the expandable member **114** may be constructed with an elastic polymer material. Suitable elastic polymer materials include but are not limited to polyurethane (PUR), polyvinyl chloride (PVC), low-density polyethylene (LDPE), polyamide, polyethylene terephthalate (PET), and the like. By way of example, a balloon may be blow molded from e.g. a pre-extruded polyurethane tubing using "hot blow molding," in which a raw tube is axially stretched, pressurized, and expanded into the inner shape of the molding tool. The raw tube is then exposed to heat, and subsequently chilled. By applying axial and radial stretch on the raw tube, the polymer's chains gain orientation (parallel alignment to stretch vectors), providing the resulting balloon with an extremely thin-walled structure with high tear strength. In some embodiments, the wall thickness of the balloon may range from 10 to 100 micrometers, and preferably from 15 to 30 micrometers. The balloon may be bonded to the proximal and distal support members **112***a*, **112***b* using any suitable means such as solvent bonding, heat bonding, ultrasound welding, clamping, etc. In use, as the balloon is inflated, it unfolds to the molded shape. When the balloon is fully filled with an inflation fluid, the balloon may exceed the molded dimensions by a certain percentage under increasing filling pressure until the maximal chain orientation is reached, then rests in a more or less non-compliant phase, not showing dimensional increase over pressure.

Any suitable inflation fluid may be used to expand or inflate the expandable member. The inflation fluid is typically inert. Exemplary inflation fluids include a liquid such as water, saline, mineral oil, or other liquids, or a gas such as air, nitrogen, carbon dioxide or other inert gases. In some embodiments, the inflation fluid may contain media that enhance the contrast of imaging by X-ray or other imaging modality. Contrast enhanced media may include positive contrast media that absorb radiation more strongly than the tissue or structure being imaged, or a negative contrast media, less strongly. The contrast enhanced media can be iodine-based or gadolinium-based. Suitable iodine-based contrast enhanced media include but are not limited to Visopaque (iodixanal, GE Healthcare), omnipaque (iohexol, GE Healthcare), Ultravist (iopromide, Berlex), or isovue (iopamidol, Bracco Diagnostics). Suitable gadolinium-based contrast media include MultiHance (gadobenate dimeglumine, Bracco Diagnostics), Omniscan (GE Healthcare), or Magnevist (Berlex Laboratories).

The inflation fluid may be introduced into the spatial volume enclosed by the expandable member **114** using e.g. a catheter (not shown), which may be supported by the proximal support member **112***a*. The distal end of the catheter may have an opening in communication with the spatial volume enclosed by the expandable member **114**. The proximal end of the catheter may be connected to a source supplying an inflation fluid. The lumen extending from the proximal end to the distal end introduces the inflation fluid into the spatial volume defined by the expandable member **114**. A valve may be coupled to the proximal end of the catheter to control the flow of the inflation fluid.

A seal member **116** may be coupled to the distal portions **106***b*, **108***b* of the first and second elongate bodies **106**, **108** to seal the moving parts and prevent the inflation fluid inside the expandable member **114** from leaking into the gaps between the moving parts of the first and second elongate bodies **106**, **108**. The seal member **116** may be an elastic balloon bonded to the distal and proximal support members **112***a*, **112***b*. Other forms of seals such as O-rings or the like may also be used.

FIGS. **5-6** illustrate exemplary brachytherapy apparatus **200** in accordance with further embodiments. The apparatus **200** is similar in many aspects to the apparatus **100** described in connection with FIGS. **1-4**. For example, the apparatus **200** may include a treatment delivery portion **102** and a handle portion **104**. The treatment delivery portion **102** may include a plurality of treatment members **110** and an expandable member **114** enclosing the plurality of treatment members **110**. The treatment members **110** may include proximal ends **110***a* coupled to a proximal support member **112***a*, distal ends **110***b* coupled to a distal support member **112***b*, and pathways between the distal and proximal ends **110***a*, **110***b* for receiving one or more radiation sources. Any suitable means can be used to move the proximal support member **112***a* or the distal support member **112***b* relative to each other. For example, the distal support member **112***b* may be coupled to a first elongate body **106**, the proximal support member **112***a* may be coupled to a second elongate body **108** which may be slidably or rotatably disposed around the first elongate body **106**. A relative movement or displacement between the first and second elongate bodies **106**, **108** in axial direction brings the proximal ends **110***a* and the distal ends **110***b* of the treatment members **110** closer or carry the two ends farther away, causing the treatment members **110** to change between a generally straight configuration and a curvilinear configuration. The expandable member **114** may be contracted or expanded using an inflation fluid. A seal member **116** may be coupled to the proximal and distal support members **112***a*, **112***b* to provide sealing between the moving parts and the inflation fluid.

The apparatus **200** may further include an extension or attachment member **118** outside the expandable member **114**. The extension member **118** may have various lengths, curvatures, or take various angles for deployment in voids of different size or configuration in the living body. The extension member **118** may have a channel adapted to receive one or more radiation sources. Alternatively, the channel in the extension member **118** may be configured for receiving a second treatment member **120** which has a pathway for receiving a radiation source. For example, the second treatment member **120** may be extended from the first elongate body **106** which may have a provided lumen extending from its proximal portion to its distal portion. The distal support member **112***b* may have a provided opening to allow the second treatment member **120** to extend through into the channel of the extension member **118**.

Be way of example, the extension member **118** may be a cervical sleeve that can fit in the uterine cervix for treatment of cervical disease. The cervical sleeve may have a rounded end portion to facilitate smooth insertion into the uterine cervix. The cervical sleeve may have a length that fits in the uterine cervix or through the cervix into the uterus. The cervical sleeve may be coupled to the distal support member **112***b* by any suitable means such as a connector **122**. The connector **122** may have a provided opening to allow e.g. a wire carrying a radiation source passing through, or a second

treatment member **120** passing through into the extension member **118**. The connector **122** may have a greater cross-section so that it stops in front of the uterine cervix as the sleeve fits in the cervix.

The extension member **118** may also be an intrauterine tandem with varied curvatures to be positioned in the uterus. The intrauterine tandem may be coupled to the distal support member **112***b* by e.g. a connector **122**. The connector **122** may have a provided opening to allow a wire carrying a radiation source or a second treatment member **120** passing through into the intrauterine tandem.

FIGS. **7** and **8** illustrate an exemplary handle portion **104** in accordance with some embodiments. The handle portion **104** may be removably coupled to the treatment delivery portion **102**. The handle **104** may include a proximal part **104***a* and a distal part **104***b*. The distal part **104***b* may be a tubular member coupled to the second elongate body **108** via a support member **124** which may be secured to the proximal portion **108***a* of the second elongate body **108**. The proximal part **104***a* of the handle **104** may be coupled to the first elongate body **106** by any suitable means such as slots, pins, or other mating features on the proximal portion **106***a* of the first elongate body **106** and the proximal part **104***a* of the handle **104**. The proximal part **104** of the handle **104** may be inserted into the distal part **104***b*. The proximal part **104***a* and the distal part **104***b* may be slidably movable relative to each other in proximal or distal directions.

The distal part **104***b* of the handle **104** may be provided with a scale **126** that includes reference such as consecutive numbers or letters to indicate the degree of relative movement between the distal part **104***b* and the proximal part **104***a*. The reference can be an indicator of the extent of expansion of the treatment members **110**. For example, a reference "0" on the scale **126** may indicate no bowing of the treatment members **110** and the treatment members **110** are in generally straight configuration. A reference "10" on the scale **126** may indicate the maximal bowing of the treatment members **110** and the treatment members **110** are in the maximal curvilinear configuration. Any reference between "0" and "10" may indicate a configuration that is in between the generally straight and the maximal curvilinear configuration. This would be beneficial to users in controlling the pathways of the radiation sources and thus the dosimetry to the target.

The handle **104** may include a lock/release mechanism **128** to limit the movement of the first and the second elongate bodies **106**, **108**. For example, the lock/release mechanism **128** may include a spring-loaded pin that may drop into and come up from a slot on the first elongate body **106**. In use, the user may press the button **128** so that the proximal part **104***a* or distal part **104***b* of the handle **104** can be moved in a proximal or distal direction, thus displacing the first and the second elongate bodies **106**, **108**. Once the treatment members **110** are in a desired curvilinear configuration, the user may release the button **128** to lock the first and second elongate bodies **106**, **108**. The handle **104** can then be detached to reduce the profile of the apparatus **100** or **200**. The handle **104** may be reusable and able to be sterilized. FIG. **8** illustrates an exploded view of the handle **104** showing the proximal part **104***a*, distal part **104***b*, and a handle support **124** to be coupled to the second elongate body **108**.

Prior to the apparatus **100** or **200** being inserted into the living body, the living body would be imaged for diagnostic and treatment selection purposes. Once selected, the apparatus would be inserted and the living body would then be imaged again for the purposes of treatment planning. Various imaging techniques may be used including computed tomography (CT), single photon emission computed tomography (SPECT), magnetic resonance imaging (MRI), magnetic resonance spectroscopy (MRS), and positron emission tomography (PET) etc. The volume enclosed by the expandable member **114** can be filled with a liquid comprising a media that enhances the contrast of imaging. The pathways of the treatment members **110** may also be filled with a media that enhances the contrast of imaging to facilitate reconstruction of images during the treatment planning process.

The brachytherapy apparatus **100** or **200** may be supplied as a kit with unassembled treatment delivery portion **102** and handle portion **104**. In use, the handle portion **104** would be attached to the treatment delivery portion **102**. The expandable member **114** would initially be in a contracted configuration. While being configured in this small form, the treatment delivery portion **102** is inserted into the living body to the intended target site.

Once in place inside the living body, the expandable member **114** is expanded with an inflation liquid via e.g. a catheter with a provided lumen in communication with the spatial volume enclosed by the expandable member. The expansion of the expandable member **114** can be determined by the amount of the inflation fluid entered into the spatial volume. A valve or other suitable means can be coupled to the catheter to control the flow of the inflation fluid. The relationship between the geometry of the expandable member **114** and the volume of the inflation fluid would be known and reproducible.

Once the expandable member **114** is filled and the valve shut, the expandable member **114** would retain its geometry for the duration of the treatment session. The handle **104** would then be used to adjust the treatment members **110** from a generally straight configuration to a curvilinear configuration, collectively forming to an "egg beater" or "rugby" like configuration. This may be achieved by pressing and holding the button **128** on the handle **104** and move e.g. the distal part **104***b* of the handle **104** forward. This action would bring the two ends of the treatment members **110** closer inside the expandable member **114** and cause the treatment members **110** to bow or expand.

Once the desired expansion of the treatment members **110** has been reached, the button **128** can be released by removing the pressure, and the position would be retained by a locking mechanism including e.g. pins and slots etc. The relationship between the moving of the handle **104** in axial directions and the radial expansion of the treatment members **110** would be known, and repeatable. The scale **126** on the handle **104** would provide an indication of the degree of expansion of the treatment members **110**.

Once the apparatus **100** or **200** is retained, the handle **104** can be detached without changing the expanded configuration of the expandable member **114** or the treatment members **110**. The handle **104** can be reattached to the treatment delivery portion **102** to make adjustments if desired. The final configuration and relationship between the expandable member **114** and the treatment members **110** can be derived using instructions for use by referencing the volume of inflation fluid inside the expandable member **114** and the expansion value of the treatment members **110**.

The apparatus **100** or **200** can be used to treat cancer in any location within the living body including, but not limited to, cervical, vaginal, endometrial, rectal, and breast diseases. The apparatus **100** or **200** can be customized to have slightly different configurations to accommodate different living body locations. For example, to treat cervical disease, a cervical sleeve **118** of proper length and angle may be coupled to the treatment delivery portion **102** (FIGS. **5-6**). A central or second treatment member **120** may be extended past the distal

end of the expandable member **114** to enter into the sleeve. In use, the cervical sleeve portion **118** would be inserted into the uterine cervix, and the expandable member **114** portion would be retained in the vagina. The expandable member **114** is then inflated, the treatment members **110** expanded in a manner as described above. For treatment of endometrial or breast diseases, the treatment delivery portion **102** may be inserted into the uterus or into a lumpectomy cavity in the breast, and an extension member **118** would not be required.

Exemplary embodiments of a brachytherapy apparatus and method have been described. The brachytherapy apparatus advantageously uses an expandable member to provide a spatial volume for treatment members which may change between a generally straight and a curvilinear configuration. The use of an expandable member eliminates the need for additional packaging which would otherwise be necessary for filling the void in the target site. The expandable member may have an expanded configuration that distances critical organs such as the bladder, rectum etc. or other healthy tissue away from the radiation source. Comfort to patients will be greatly improved as compared to conventional apparatuses which use heavier metal parts in direct contact with the patient's tissue. Treatment planning will also be improved. A plurality of treatment members may be provided so that the radiation dose would not be centralized but would be more flexible to adjust. This allows sparing critical organs adjacent to the target. Better dose distribution or more flexible dose distribution can be achieved with the use of the expandable member in the target site.

Those skilled in the art will appreciate that various modifications may be made within the spirit and scope of the invention. All these or other variations and modifications are contemplated by the inventors and within the scope of the invention.

What is claimed is:

1. An apparatus for brachytherapy comprising:

a distal support member;

a proximal support member movable relative to the distal support member;

a plurality of elongate treatment members having distal first locations coupled to the distal support member, proximal second locations coupled to the proximal support member, and pathways between the proximal second locations and the distal first locations adapted to receive one or more radiation sources therealong, each of said treatment members being movable between a generally straight configuration and a curvilinear configuration;

an expandable member enclosing the plurality of the treatment members, the distal support member, and the proximal support member, the expandable member being-inflatable by an inflation medium from a contracted configuration to an expanded configuration, wherein the distal support member and the proximal support member are movable in the expanded configuration to adjust the plurality of elongate treatment members between the generally straight configuration and the curvilinear configuration;

a catheter configured to introduce the inflation medium to inflate the expandable member to provide the expanded configuration;

a first elongate body having a distal portion and a proximal portion, a second elongate body having a distal portion and a proximal portion, the second elongate body being disposed around and axially movable relative to the first elongate body, wherein the distal support member is coupled to the distal portion of the first elongate body, and the proximal support member is coupled to the distal portion of the second elongate body; and

a seal member coupled to the distal portions of the first and second elongate bodies within the expandable member such that the seal member provides sealing that prevents the inflation medium from leaking into moving parts of the first and second elongate bodies.

2. The apparatus of claim **1** wherein the expandable member is configured to provide an expanded configuration in a generally cylindrical shape.

3. The apparatus of claim **2** wherein the expanded configuration in the generally cylindrical shape has a transverse dimension ranging from 2 to 10 cm.

4. The apparatus of claim **1** wherein the expandable member is configured to provide an expanded configuration in a generally spherical shape.

5. The apparatus of claim **4** wherein the expandable member in the generally spherical shape has a transverse dimension ranging from 2 to 10 cm.

6. The apparatus of claim **1** wherein the expandable member is constructed with a material comprising a polymer selected from the group consisting of polyurethane (PUR), polyvinyl chloride (PVC), low-density polyethylene (LDPE), polyamide, and polyethylene terephthalate (PET).

7. The apparatus of claim **1** wherein the expandable member in the contracted configuration has a thickness ranging from 15 to 30 micrometers.

8. The apparatus of claim **1** which comprises 2-20 elongate treatment members.

9. The apparatus of claim **1** wherein the plurality of the treatment members in the curvilinear configuration collectively provide a generally "egg beater" configuration.

10. The apparatus of claim **1** further comprising a handle portion coupled to the proximal portions of the first and second elongate bodies, the handle portion being adapted to axially move the first and second elongate bodies relative to each other.

11. The apparatus of claim **10** wherein the handle portion is removably coupled to the proximal portions of the first and second elongate bodies.

12. The apparatus of claim **11** wherein the handle comprises a scale including reference that indicates the degree of the movement of the treatment members.

13. The apparatus of claim **11** further comprising a lock and release mechanism to limit the movement of the treatment members.

14. The apparatus of claim **1** further comprising an extension member outside the expandable member and coupled to the distal support member, the extension member having a pathway adapted to receive one or more radiation sources.

15. The apparatus of claim **14** wherein the extension member is configured to be deployed in the vagina cervix.

16. The apparatus of claim **14** wherein the extension member has a curvature and is configured to be deployed in the uterus.

17. An apparatus for brachytherapy comprising:

a first elongate body having a distal portion and a proximal portion;

a second elongate body having a distal portion and a proximal portion, the second elongate body being disposed around and axially movable relative to the first elongate body;

a plurality of elongate treatment members having distal first locations coupled to the distal portion of the first elongate body, proximal second locations coupled to the distal portion of the second elongate body, and pathways between the proximal second locations and the distal

first locations adapted to receive one or more radiation sources therealong, each of the treatment members being movable between a generally straight configuration and a curvilinear configuration;

an expandable member enclosing the plurality of the treatment members, the distal portion of the first elongate body, and the distal portion of the second elongate body, the expandable member being inflatable by an inflation medium from a contracted configuration to an expanded configuration, wherein the distal portions of the first and the second elongate bodies are movable in the expanded configuration to adjust the plurality of elongate treatment members between the generally straight configuration and the curvilinear configuration;

a catheter configured to introduce the inflation medium to inflate the expandable member to provide the expanded configuration;

an elongate extension member extending outside the expandable member and coupled to the distal portion of the first elongate body, the extension member having a pathway adapted to receive one or more radiation sources therealong; and

a seal member coupled to the distal portions of the first and second elongate bodies within the expandable member such that the seal member provides sealing that prevents the inflation medium from leaking into moving parts of the first and second elongate bodies.

18. The apparatus of claim **17** further comprising a second treatment member extended through the first elongate body and into the pathway of the extension member, the second treatment member having a pathway adapted to receive one or more radiation sources therealong.

19. The apparatus of claim **18** wherein the extension member comprises a cervical sleeve to be fit in the uterine cervix for treatment of cervical diseases.

20. The apparatus of claim **18** wherein the extension member comprises a curved intrauterine tandem to be positioned in the uterus for treatment of endometrial diseases.

21. An apparatus for brachytherapy comprising:

a proximal support member;

a distal support member;

one or more treatment members each having a distal first location coupled to the distal support member, a proximal second location coupled to the proximal support member, and a pathway between the distal first location and the proximal second location adapted to receive one or more radiation sources therealong;

an expandable member enclosing the one or more treatment members, the proximal support member and the distal support member, the expandable member being inflatable by an inflation medium from a contracted configuration to an expanded configuration wherein the distal support member and the proximal support member are movable in the expanded configuration to adjust the one or more treatment members between the generally straight configuration and the curvilinear configuration, and having a thickness ranging from 15 to 30 micrometers in the contracted configuration, wherein the one or more treatment members are spaced apart from the expandable member at least in the expanded configuration;

a catheter configured to introduce the inflation medium to inflate the expandable member to provide the expanded configuration;

a first elongate body having a distal portion and a proximal portion, a second elongate body having a distal portion and a proximal portion, the second elongate body being disposed around and axially movable relative to the first elongate body, wherein the distal support member is coupled to the distal portion of the first elongate body, and the proximal support member is coupled to the distal portion of the second elongate body; and

a seal member coupled to the distal portions of the first and second elongate bodies within the expandable member such that the seal member provides sealing that prevents the inflation medium from leaking into moving parts of the first and second elongate bodies.

22. The apparatus of claim **21** wherein the expandable member is constructed with a material comprising a polymer selected from the group consisting of polyurethane (PUR), polyvinyl chloride (PVC), low-density polyethylene (LDPE), polyamide, and polyethylene terephthalate (PET).

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