

[54] APPARATUS FOR TREATING THE WALLS AND FLOOR OF THE PELVIC CAVITY WITH RADIATION

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[63] Continuation-in-part of Ser. No. 151,425, June 9, 1971, abandoned.

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[51] Int. Cl. **A61n 5/10**

[58] Field of Search 128/1.1, 1.2; 250/108 FS, 250/519, 108 WS

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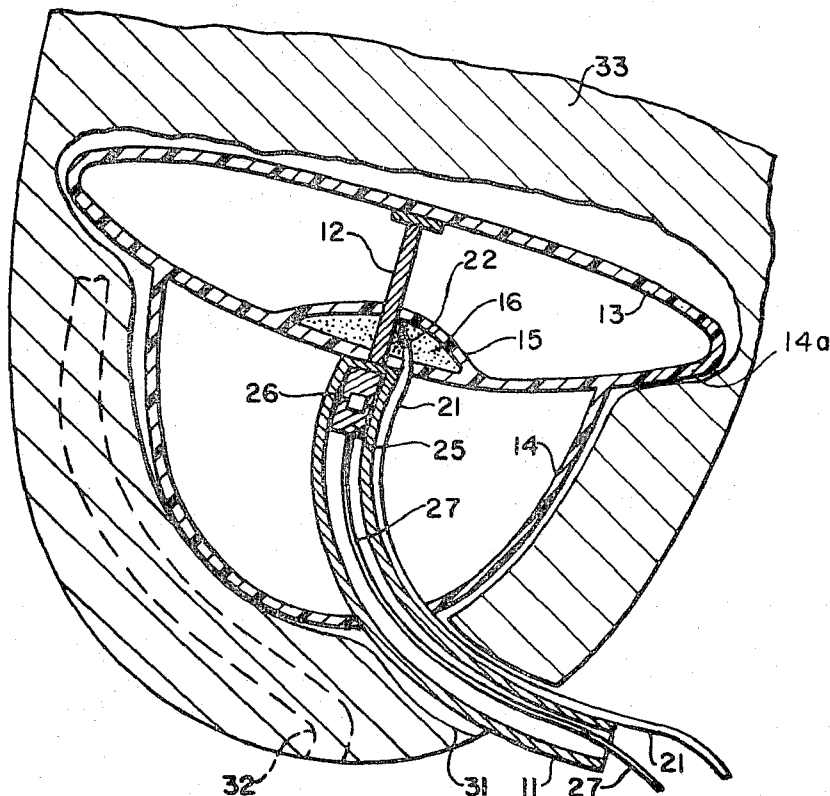
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[57] **ABSTRACT**

An apparatus for treating carcinoma of the walls and floor of the pelvic cavity. An elongated tube has an inner end adapted to be placed in the pelvic cavity and an outer end adapted to extend through to the outside of the body. Radioactive material is placed at the inner end. An inner balloon above the radioactive material is inflated to hold a body of liquid shielding material such as mercury. A lower balloon portion beneath the inner balloon spaces areas to be treated such as the walls and floor of the pelvic cavity from the radioactive material. An upper balloon portion above the inner balloon keeps the intestines out of the pelvic cavity and away from the radioactive material. The apparatus is inserted into the pelvic cavity through an abdominal incision. When treating a woman for carcinoma in the walls and floor of the pelvic cavity the tube is moved through the vaginal passage from the inside outwardly. When treating a woman with a closed vaginal passage, as may result from surgery, or when treating a man, such as for carcinoma of the bladder, the tube will pass out of the body through a lower abdominal incision. Following treatment, all balloons are deflated so that the apparatus can be withdrawn through the vaginal passage or the lower abdominal incision, as the case may be.

25 Claims, 5 Drawing Figures



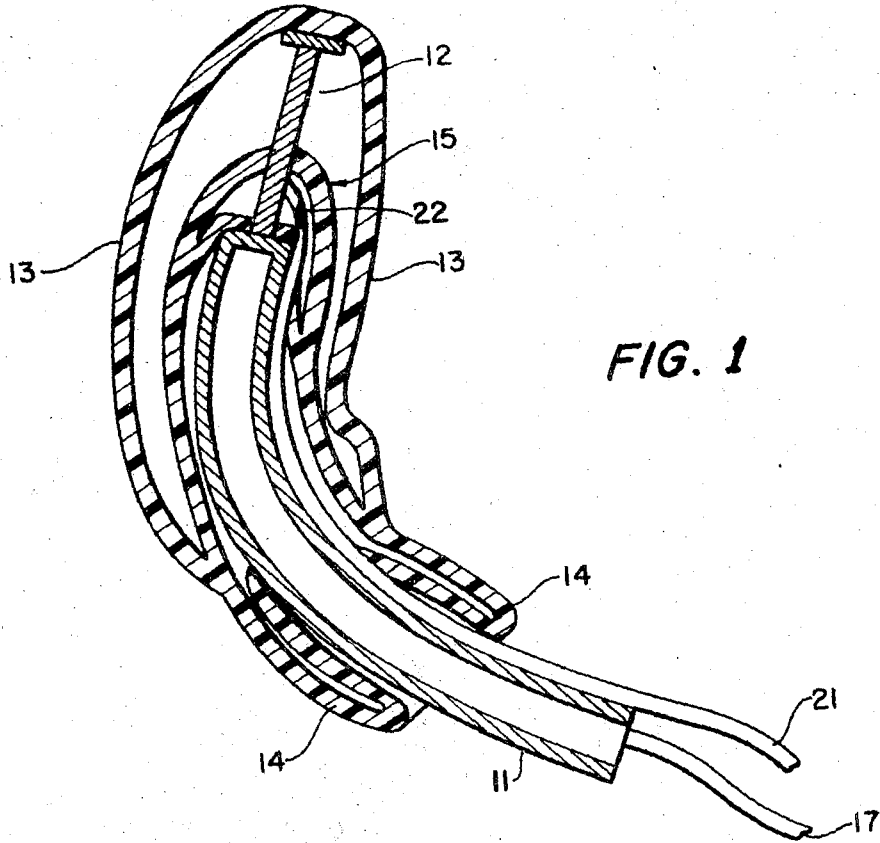


FIG. 1

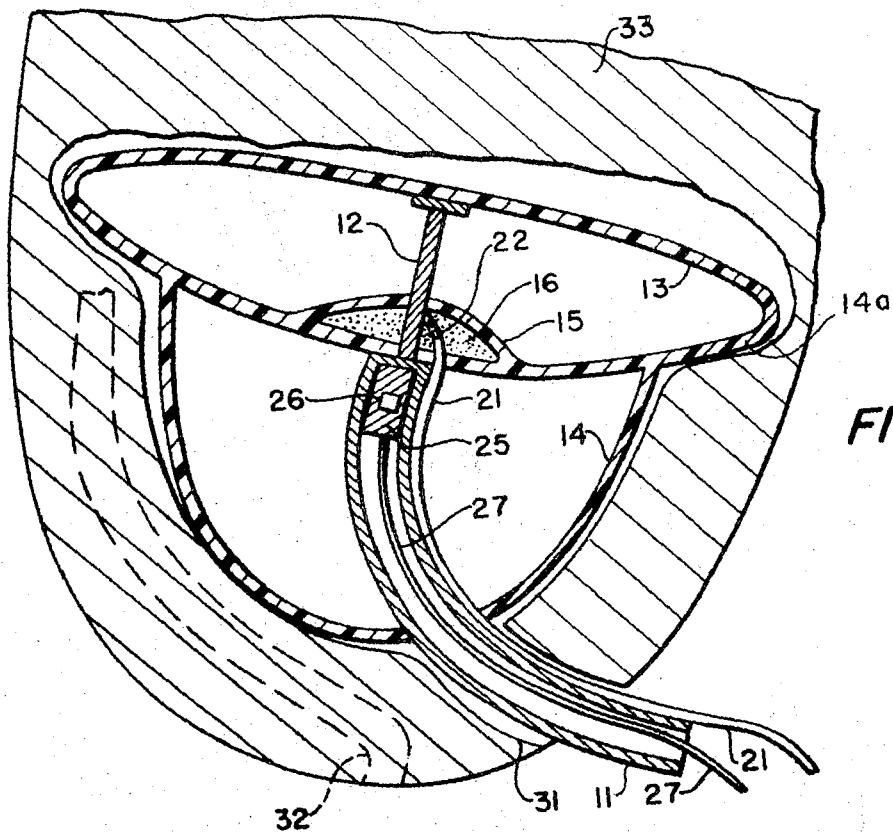


FIG. 2

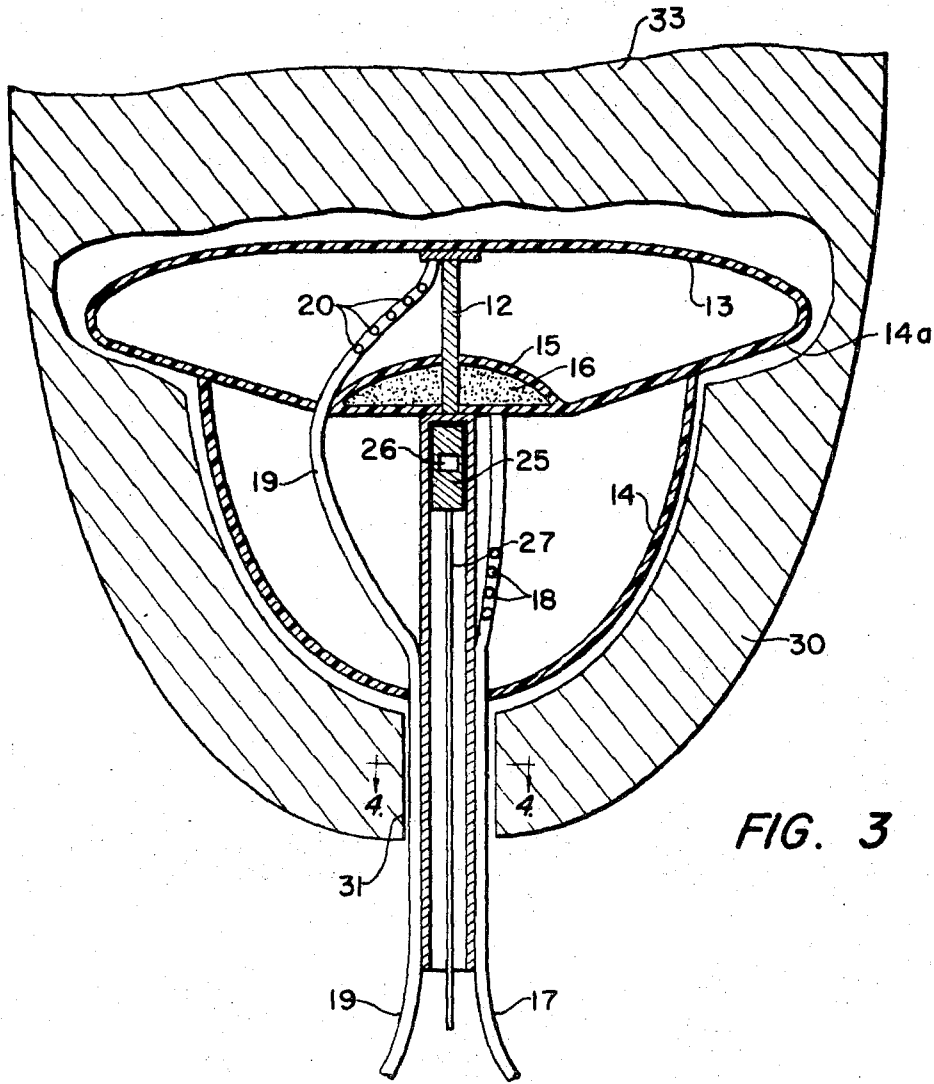


FIG. 3

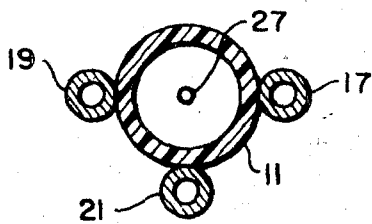


FIG. 4

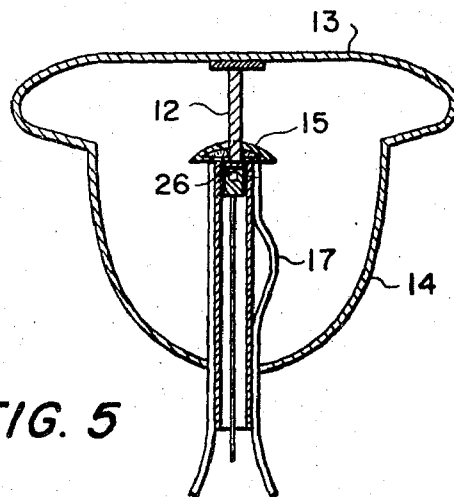


FIG. 5

APPARATUS FOR TREATING THE WALLS AND FLOOR OF THE PELVIC CAVITY WITH RADIATION

RELATED APPLICATION

This application is a continuation-in-part of my earlier application Ser. No. 151,425, filed June 9, 1971, now abandoned.

BACKGROUND OF THE INVENTION

This invention relates to the treatment of carcinoma, or cancerous tissues, by the insertion of radioactive material into a body cavity in the vicinity of the cancerous tissues. More particularly, this invention is concerned with an apparatus for inserting radioactive material into the pelvic cavity to treat the walls and floor thereof with ionizing radiation from radioactive material as required for example in a woman following the removal therefrom of the female reproductive organs or in a man to treat carcinoma of the bladder.

There are two recognized methods of treating cancer, namely the removal of cancerous tissue by surgery and the application of X-rays or radiation from radioactive material to the cancerous tissues to destroy them. In many cases, both of these methods are employed to advantage. This is particularly true in cancer of the cervix in adult females where the cancerous growth might have spread to other structures and organs of the surrounding pelvic walls so that the surgeon cannot be certain that he has removed all cancerous tissues by an operation to remove the uterus, ovaries, or other affected organs. Furthermore, many structures affected by cancer cannot be removed. For example, in both early and advanced nature, the cancer cells have already lodged in lymph nodes surrounding the pelvic region. It is therefore desirable and often necessary that post-operative radiation by radioactive material or X-ray of the pelvic walls be carried out with the purpose of destroying all cancer cells not removed by surgery.

Conventional treatment of carcinoma of the cervix involves the use of intravaginal and intrauterine devices, supplemented by teletherapy to the lateral pelvic walls. However, these devices while satisfactory for treating the cervix, are no good for treating the walls and floor of the pelvic cavity after removal of the cervix and other organs. If used for this purpose, the radiation dose applied to the structures in the middle of the pelvis in the vicinity of the vagina is too high, causing undesirable damage while the radiation dose delivered to the far lateral or upper portions of the pelvic walls where the cancerous tissues may reside is too low to be effective to cure cancer. There is too much irradiation of normal structures not involved by cancer such as the skin, bones, muscles, small intestines, urinary bladder, rectum and other tissues exposed in close proximity to the radioactive material and too little at remote parts of the pelvic walls where the cancerous tissue may be. Further, uniform doses of radiation could not be applied to the same patient from time to time due to the difficulties of reproducible placement of such old type radioactive material holders and due to the absence of visual inspection of the affected areas. Hence, when only intravaginal devices were available for inserting radioactive material into the body, the only method of treating the walls and floor of the pelvic cavity following removal of the female organs was bombardment

with radioactive material from outside the body. But this was almost never successful in eliminating the cancerous tissue.

In my U.S. Pat. No. 2,959,166, issued Nov. 8, 1960, there is disclosed and claimed an apparatus for overcoming these disadvantages of the earlier intravaginal and intrauterine devices. With the device according to my said patent, the apparatus containing the radioactive material is inserted immediately following the removal of the reproductive organs and through the same abdominal incision before the same is closed up. The device is left in place for the necessary length of time, for example, several days, and then removed by additional abdominal surgery. This device overcame several of the disadvantages with the earlier devices. Most importantly it permitted a high enough level of radiation to be applied to all parts of the pelvic floor and walls without excessive doses to other areas. Also, it permitted direct viewing of the areas to be treated, it permitted proper placement of the radioactive material relative to the areas being treated whereby the dosage could be more properly controlled, and it permitted better shielding of non-affected areas. Moreover, it permitted greater control of the dosage from patient to patient and it eliminated the need for supplementary X-ray treatment.

However, notwithstanding these significant advantages of the apparatus in my earlier patent, certain disadvantages remain. First, the insertion of the device is complicated by the fact that it must be directly attached to the bones. Secondly, the device is somewhat complex in that there are a number of different moving mechanical parts which must be adjusted in order to fit the device into the patient. Thirdly, additional surgery, including making another large incision, is necessary to remove the device. Further, with my previous device handling of the radioactive material was increased since the material had to be placed into the apparatus before the abdominal incision was closed.

Thus, although my earlier device represented a significant advancement in the radiation of the pelvic cavity area, there still exists a need for further improvements.

SUMMARY OF THE INVENTION

The purpose of this invention is to provide a new and improved apparatus for treating the pelvic walls and floor with radiation according to the transabdominal method.

This purpose of the present invention is achieved by providing an apparatus which can be inserted through an abdominal incision, held in place by inflatable members and wherein, upon the termination of treatment, the inflatable members can be deflated, whereby the entire apparatus can be withdrawn without additional surgery.

According to the present invention, there is provided an elongated tube having a means for locating radioactive material at its inner end and having inflatable members located at this inner end. In accordance with a preferred embodiment, these inflatable members include a small inner inflatable balloon located above the inner end of the tube and containing therein a flowable shielding material such as mercury. A lower, or spacing balloon portion positioned beneath the inner balloon is shaped like a portion of a sphere thereby spacing the areas to be treated a predetermined distance from the

radioactive material. A third, or upper balloon portion above the inner balloon keeps the intestines out of the pelvic cavity and away from the radioactive material. The lower and upper balloon portions may be separated from each other by a dividing wall or they may be a single space. In practice, the inflatable members are all inflated after which the apparatus is inserted into the patient through an abdominal incision with the elongated tube being pushed downwardly outwardly through a lower smaller body cavity such as the vaginal passage or a small lower abdominal wall incision. The main abdominal incision is then closed and radioactive material is inserted through the tube to the said inner end. Following treatment, all inflatable members are deflated and the apparatus is simply pulled through a plastic guide tube slipped over the tubes in the body cavity. Where appropriate, the vaginal passage will be used for outward passage of the elongated tube since this is a natural body cavity and absolutely no further surgery will be required when removing the apparatus. However, where this is not available such as in the case of a woman without a vaginal passage or in the case of a man, the elongated tube will be passed outwardly through a lower abdominal wall incision made for that purpose. In this latter case, further surgery for removing the apparatus is still eliminated, since this lower abdominal incision will close by itself following removal of the apparatus. At most a clamp or a few stitches may be required to hold it closed, but these minor steps do not constitute surgery.

Thus, the apparatus provides significant new advantages. By using inflatable positioning and spacing members and/or by using a liquid shielding material such as mercury or the like, all fluids can be withdrawn from the inflatable members, that is both the air and the mercury, to enable deflation of the entire apparatus to permit extraction thereof through a body cavity. Uniformity of dosage is achieved by the use of the lower balloon portion which may be constructed such that when enlarged it is a portion of a sphere with the radioactive material at the center thereof. Radioactive material handling is reduced since it need not be handled for insertion until after the apparatus is in place in the patient. No further surgery is necessary to remove the apparatus. And of course the apparatus retains all advantages of my earlier apparatus in overcoming the disadvantages of the earlier intravaginal or intrauterine methods.

Thus, it is an object of this invention to provide a new and improved apparatus for inserting a radioactive material into a body cavity.

It is another object of this invention to provide a new and improved apparatus for treating carcinoma of the walls and floors of the pelvic cavity.

It is another object of this invention to provide a new and improved radiation applicator having improved shielding means.

It is another object of this invention to provide a new and improved apparatus for applying radiation including means for significantly improving dosage uniformity.

It is another object of this invention to provide a new and improved apparatus for the transabdominal method of treating the walls and floor of the pelvic cavity with radiation in which the apparatus is inserted through a surgical abdominal opening, positioned in the cavity for the necessary length of time, and then re-

moved without further surgery through a body cavity such as the vaginal passage or a lower abdominal incision.

It is another object of this invention to improve the transabdominal method of treating the walls and floor of the pelvic cavity by radiation by providing an arrangement in which the radioactive material need not be inserted into the apparatus until after the apparatus is positioned within the pelvic cavity of the patient.

It is another object of this invention to provide a new and improved apparatus for applying radiation to the metastatic areas within the pelvic cavity for the treatment of carcinoma, which apparatus solves one or all of the problems to which the preceding objects are directed.

Other objects and advantages of the present invention will become apparent from the detailed descriptions to follow, together with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

There follows a detailed description of a preferred embodiment of the invention, to be read together with the accompanying drawings.

FIG. 1 is a longitudinal sectional view of an apparatus constructed in accordance with the features of the present invention with the parts in the collapsed condition and absent the radiation source.

FIG. 2 is a view similar to FIG. 1 but showing the apparatus inflated and inserted and viewing the same in the sagittal plan of the patient.

FIG. 3 is a frontal view of the apparatus in use.

FIG. 4 is a cross-sectional view taken along lines 4-4 of FIG. 3.

FIG. 5 is a longitudinal sectional view similar to FIG. 3 but showing a modification of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

There follows a detailed description of the preferred embodiments in which like numerals represent like elements throughout the several views.

Referring now to the figures, there is shown an inflatable radiation applying apparatus 10 comprising an elongated tube 11 of a stiff material. Attached to an inner end of the tube 11 is a stiff rod 12. An upper inflatable balloon portion 13 is connected to the end of tube 11 and extends to the end of the rod 12 and includes an annular shoulder portion 14a around the outside thereof to facilitate positioning of the device within the pelvic cavity. Formed integrally with this upper balloon portion 13 is an inner shielding balloon 15 containing a radiation shielding liquid 16. In the present case, this liquid is mercury. Below the upper balloon portion 13 and the inner balloon 15 is a lower, or spacing balloon portion 14. The balloons should preferably be made of a material which, although airtight, flexible, distensible and collapsible, is not stretchable. By using a non-stretchable material one can control the final inflated size of the balloons within close limits, hence enhancing control and uniformity of radiation dosage. A suitable material for the balloons would be a rubberized fabric or the material used in baby "plastic" wet pants. Another suitable material would be molded plastic made thin enough to collapse against the tube as shown in FIG. 1. Other examples will be apparent. Thus, in the collapsed conditions in

FIG. 1, the balloon material is of the same size as in the expanded condition of FIGS. 2 and 3. Referring to FIGS. 3 and 4 in the illustrated embodiment, air is delivered to and removed from the lower balloon portion 14 by means of an air tube 17 which communicates with the lower balloon 14 at openings 18. Air is supplied to and removed from the upper balloon portion 13 through air tube 19 which communicates with the interior of balloon portion 13 through openings 20. Referring to FIGS. 1, 2 and 4, mercury is supplied to and removed from balloon 15 through tube 21 which communicates with the interior of balloon 15 through openings 22. The tubes 17, 19 and 21 are cemented to the exterior of tube 11.

The radioactive material is located in a cavity 26 within a radioactive material carrier 25. This carrier 25 has a cable 27 extending therefrom out through the exterior end of the tube 11. This cable may be in the form of a rod having sufficient stiffness so that the carrier 25 with the radioactive material therein can be pushed up through the tube 11, but flexible enough so that the cable 27 can bend around the curve in tube 11.

The apparatus is used in the following manner in treating carcinoma of the walls and floor of the pelvic cavity of a woman following removal of the female reproductive organs. Before using the apparatus of the present invention, the surgeon will have opened the abdomen of the patient by an incision of such size and shape to permit the removal of the diseased female reproductive organs which are affected by cancer. After the necessary surgical procedures have been completed, but before the abdominal incision has been closed, the doctor will take an apparatus of the present invention, inflate the lower and upper balloon portions by introducing air through the tubes 17 and 19, respectively, and then fill the shielding balloon with a flowable shielding material such as mercury through the tube 21. While in this inflated condition, the apparatus is then inserted into the abdominal incision, into the pelvic cavity, passing the tube 11 out of the body through the vaginal passage. The lower ends of the tubes 17, 19 and 21 are cemented to the outer surface of tube 11 so that they move with the tube 11 outwardly through the vaginal passage 31. However, after the apparatus has been positioned, the tubes may be extended. For example, it may be desirable to connect the air and mercury tubes to suitable pressure monitoring gauges.

Next, the abdominal incision is permanently closed. The position of the apparatus within the cavity may then be checked by X-rays. After all positioning has been completed, and the patient is in her room, the radioactive material 26 within the carrier 25 is then introduced into the tube 11 and pushed up to the inner end of the tube 11 as shown in FIG. 2 and 3. The insertion procedure is now completed and the apparatus may remain in the patient for the necessary period of time, perhaps several days. FIGS. 2 and 3 illustrate the apparatus inserted within the pelvic cavity. The rectal opening 32 is visible in FIG. 2 and the small intestines 33 are shown above the apparatus. The small intestines are now shielded from the radiation by virtue of the mercury shield 16 extending across the inner end of the tube 11 and the displacement away from the radioactive source provided by balloon portion 13.

The lower balloon portion 14 now assumes the shape of a generally spherical portion with the center of the

sphere at the center of cavity 26. In this manner, all pelvic walls are spaced a fixed distance from the radioactive material.

In a preferred arrangement, the source is cesium-137, although it could be any suitable radioactive material. The radius of the spherical portion formed by the inflated lower balloon portion 14 would be 5 centimeters in a preferred arrangement of the invention, or 4 centimeters, or any necessary distance.

Numerous variations are possible within the scope of the invention. For example, the advantage of constant spacing provided by the lower balloon portion 14 could be provided even without the upper balloon portion 13 or the shield 16.

Removal of the apparatus from the patient takes place in the following manner. First, the radiation material is removed by pulling the cable 27 to remove the radioactive material containing carrier 25. Next, the tubes 17 and 19 are opened to remove air from balloon portions 14 and 13; and the tube 21 is opened to remove mercury from the balloon 15. The balloons then collapse against the tube 11 and the rod 12. The apparatus now assumes the collapsed position as shown in FIG. 1 and it is removed by simply withdrawing it out through a plastic guide inserted into the vaginal passage and around the four tubes.

When used on a woman with a blocked vaginal passage or on a man, for example to treat carcinoma of the bladder, the operation is basically the same as described above except that the tubes extend out of the body and are subsequently removed through an abdominal incision rather than through the vaginal passage. Possibly, but not necessarily, the curvature of the tube will be varied for use with a lower abdominal incision opening.

FIG. 5 illustrates a modification of the invention. In this case the lower and upper balloon portions form a common space. The tube 19 can be eliminated and of course the mercury balloon is now attached only to the inner end of the tube 11, i.e., it is not integral with the upper balloon portion 13 as in the first embodiment. In other respects however, the structure and operation of this modified apparatus is the same as the first embodiment.

Although the invention has been described in considerable detail with respect to a preferred embodiment thereof, it will be apparent that the invention is capable of numerous modifications and variations apparent to those skilled in the art without departing from the spirit and scope of the invention.

I claim:

1. An apparatus for treating carcinoma of the walls and floor of the pelvic cavity comprising: an elongated hollow tube having a closed inner end adapted to be located in the pelvic cavity, the tube adapted to extend through a body opening to the outside of the body and including an opened outer end adapted to be located outside the body, means for locating radioactive material in the tube at the vicinity of said inner end by passing the radioactive material into the opened outer end of the tube and through the tube, positioning means including at least one inflatable balloon having a spacing portion attached to and surrounding the exterior of the tube in the vicinity of the said inner end thereof, said balloon, when inflated, spacing the walls and floor of the pelvic cavity from the radioactive material to position the radioactive material a generally uniform distance

from all wall and floor surfaces subject to the radiation, while the tube extends through the body opening, and means for introducing fluid into the inflatable balloon spacing portion to expand the same and for removing fluid from the inflatable balloon spacing portion to collapse the same to permit the removal of the apparatus through the body opening.

2. An apparatus according to claim 1, wherein the balloon is of a material which is flexible and non-stretchable.

3. An apparatus according to claim 1, including a shielding balloon adjacent the inner end of the tube, means for introducing into and removing from said shielding balloon a flowable radioactive shielding material, said shielding balloon being expandable in a direction transverse to the longitudinal direction of the elongated tube such that the shielding material in the shielding balloon extends transversely to shield the portion of the body of the patient beyond the said inner end of the tube from the radioactive material.

4. An apparatus according to claim 3, said at least one balloon including an upper inflatable balloon portion, said shielding balloon being formed integrally with the upper balloon portion such that when the upper inflatable balloon portion is inflated, its walls, in expanding, extend the shielding balloon transversely relative to the axis of the tube.

5. An apparatus according to claim 4, including a stiff rod attached to and extending axially away from the inner end of the tube, said shielding balloon and said upper inflatable balloon portion being attached to and surrounding said rod, such that in the collapsed condition, when fluid has been removed from both of said balloon portions, the shielding balloon and the upper inflatable balloon portion collapse onto the rod in a shape to facilitate removal through the body cavity.

6. An apparatus according to claim 4, wherein said at least one balloon portion includes a spacing inflatable balloon portion encircling the side of the tube, said spacing balloon portion having a surface which is spherical when inflated, all about the tube to define a portion of a sphere with radioactive source material at the center thereof.

7. An apparatus according to claim 4, said upper and lower balloon portions being separate enclosures, and said means for introducing fluid into and removing fluid from said at least one balloon portion including separate tubes for each of said upper and lower balloon portions for introducing fluid into and removing fluid therefrom, each of said separate tubes extending alongside the elongated tube.

8. An apparatus according to claim 1, wherein said at least one balloon includes a spacing inflatable balloon portion encircling the side of the tube, said spacing balloon constructed to inflate and to collapse and such that when inflated, its surface all about the tube defines generally a portion of a sphere with the radioactive source material at the center thereof.

9. An apparatus according to claim 8, wherein, in the collapsed condition, the spacing balloon portion collapses around the tube, to facilitate removal through the body cavity.

10. An apparatus according to claim 8, said balloon being of a material which is flexible and non-stretchable.

11. An apparatus according to claim 10, said positioning means including an upper balloon portion

formed integrally with the spacing balloon portion, the upper balloon portion being larger in a direction transverse to the tube than the spacing balloon, the two balloon portions thus defining at the joining outer peripheries thereof a shoulder, and the two balloon portions forming a common cavity.

12. An apparatus according to claim 1, said positioning means including an upper portion, at least a part of which is located beyond the said inner end of the tube for spacing from the radioactive material the portion of the patients body beyond the said inner end of the tube.

13. An apparatus according to claim 12, said upper portion being circular in a direction transverse to the tube axis and extending farther from the tube than the spacing balloon portion and defining with the spacing balloon portion a shoulder to assist in positioning the balloon in the pelvic cavity.

14. An apparatus according to claim 13, said upper and spacing balloon portions being separate cavities and said means for introducing fluid comprising separate fluid tubes for introducing air into and removing air from each of them.

15. An apparatus according to claim 13, said upper and spacing balloon portions forming a common cavity and said means for introducing fluid comprising a single fluid tube for introducing air into and removing air from the cavity.

16. An apparatus according to claim 1, said elongated hollow tube being curved to pass from the pelvic cavity out through the vaginal opening of a female patient.

17. An apparatus for treating carcinoma in the walls and floor of the female pelvic cavity comprising: an elongated tube having a closed inner end adapted to be located in the pelvic cavity, the tube adapted to extend through the vaginal passage to an open outer end located outside of the body, means for locating radioactive material in the tube in the vicinity of said inner end by passing the radioactive material into the tube through the open outer end thereof, positioning means including at least one inflatable balloon attached to and surrounding the exterior of the tube in the vicinity of the inner end thereof, said balloon, when inflated, spacing the walls and floor of the pelvic cavity from the radioactive material to position the radioactive material a generally uniform distance from all wall and floor surfaces subject to the radiation, while the tube extends through the vaginal passage, and means for introducing fluid into the inflatable balloon to expand the same and for removing fluid from the inflatable balloon to collapse the same to permit removal of the apparatus through the vaginal passage.

18. An apparatus according to claim 17, wherein the balloon is of a material which is flexible and non-stretchable.

19. An apparatus according to claim 17, including a shielding balloon adjacent the inner end of the tube, means for introducing into and removing from said shielding balloon a flowable radioactive shielding material, said shielding balloon being expandable in a direction transverse to the longitudinal direction of the elongated tube such that the shielding material in the shielding balloon extends transversely to shield the portion of the body of the patient beyond the said inner end of the tube from the radioactive material.

20. An apparatus according to claim 17, wherein said at least one balloon includes a spacing inflatable bal-

loon portion encircling the side of the tube, said spacing balloon constructed such that when inflated, its surface all about the tube defines generally a portion of a sphere with the radioactive source material at the center thereof.

21. An apparatus according to claim 17, said balloon including an upper portion, at least a part of which is located beyond the said inner end of the tube for spacing from the radioactive material the portion of the patients body beyond the said inner end of the tube.

22. An apparatus according to claim 21, said upper portion being circular in a direction transverse to the tube axis and extending farther from the tube than the spacing balloon portion and defining with the spacing balloon portion a shoulder to assist in positioning the balloon in the pelvic cavity.

23. An apparatus according to claim 22, said upper and spacing balloon portions being separate cavities and said means for introducing fluid comprising separate fluid tubes for introducing air into and removing air from each of them.

24. An apparatus according to claim 22, said upper and spacing balloon portions forming a common cavity and said means for introducing fluid comprising a single fluid tube for introducing air into and removing air from the cavity.

25. An apparatus for treating carcinoma of the walls

and floor of the pelvic cavity of a female comprising, an elongated hollow tube having a closed inner end and an open outer end, said tube being curved to extend from said open outer end outside of the body through the vaginal passage to said closed inner end in the pelvic cavity, an upper inflatable balloon portion connected to the tube and located above the inner end of the tube to space the intestines from the pelvic cavity, a shielding inflatable balloon portion connected to the tube and located directly above the said inner end of the tube, means for introducing a radioactive material through the open outer end of the tube and there-through to the inner end thereof while the inner end is located in the pelvic cavity, a spacing balloon portion connected to and surrounding the tube and having a surface which is spherical when inflated, said portion extending all around the tube to define, when expanded, a part of a sphere with the center thereof located at the location of the radioactive material at the said inner end of the tube to space the walls and floor of the pelvic cavity a certain distance from the radioactive material, and separate tubes for introducing fluid into and removing fluid from each of the upper and spacing balloon portions and said shielding balloon portion, each of said separate tubes extending alongside the said elongated tube.

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