

June 2, 1959

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2,888,917

CERVICO-VAGINAL RADIUM APPLICATOR

Filed Sept. 8, 1954

3 Sheets-Sheet 1

Fig. 1.

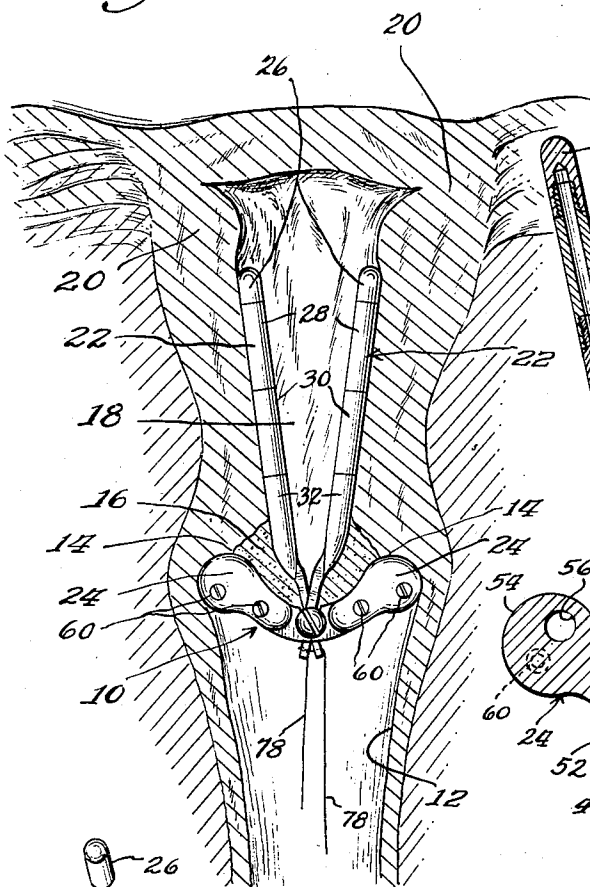


Fig. 2.

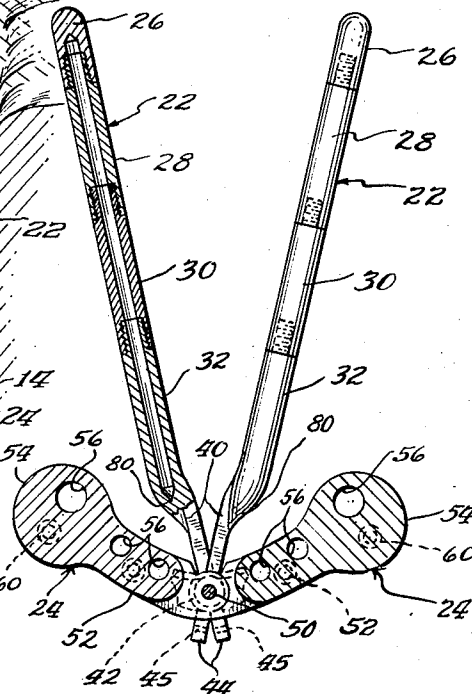


Fig. 3.

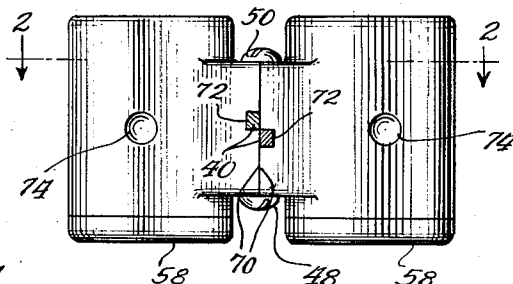
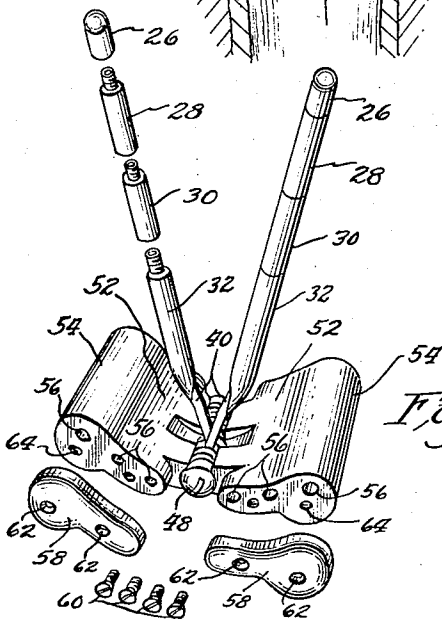


Fig. 4.



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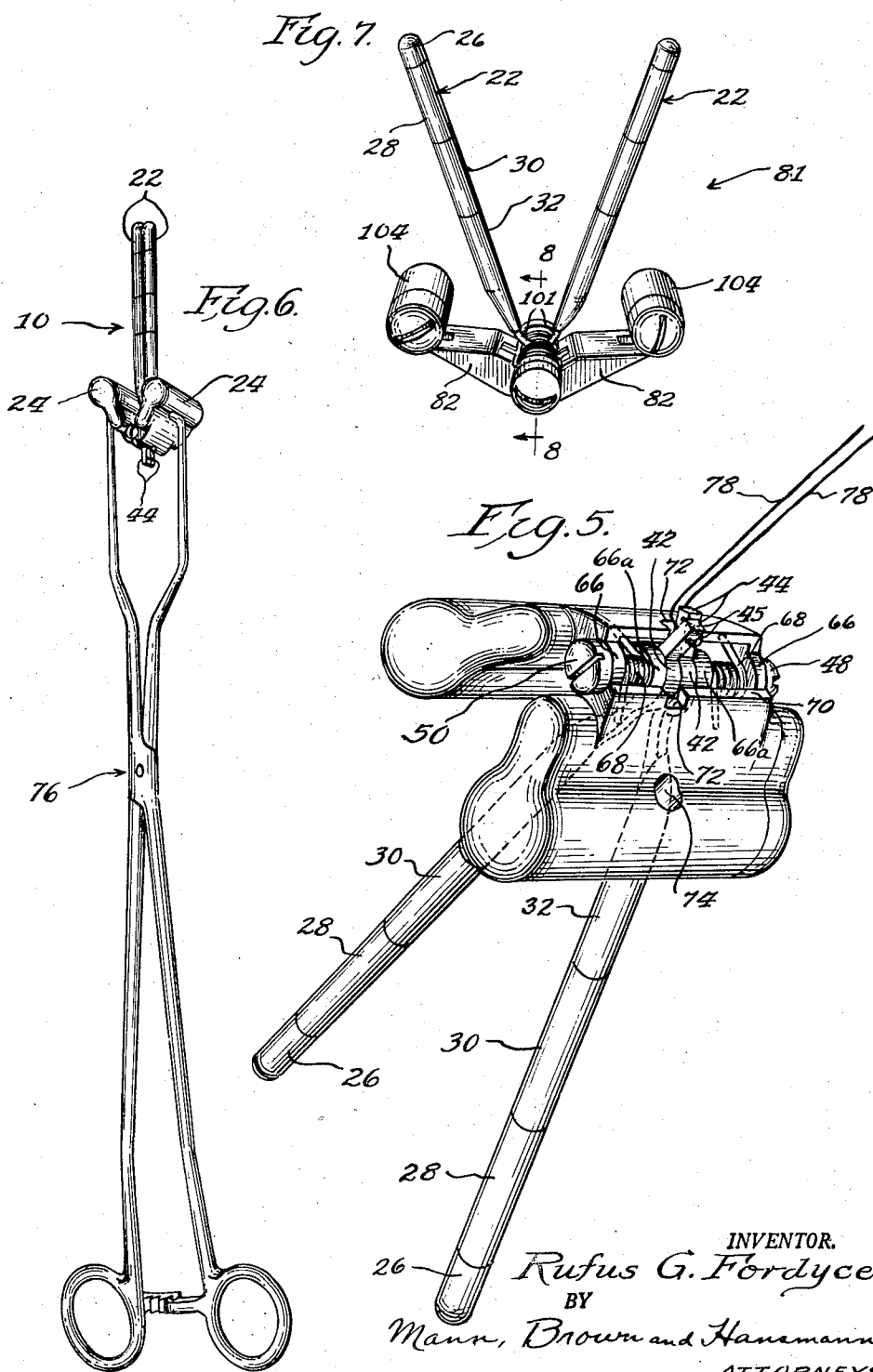
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3 Sheets-Sheet 3

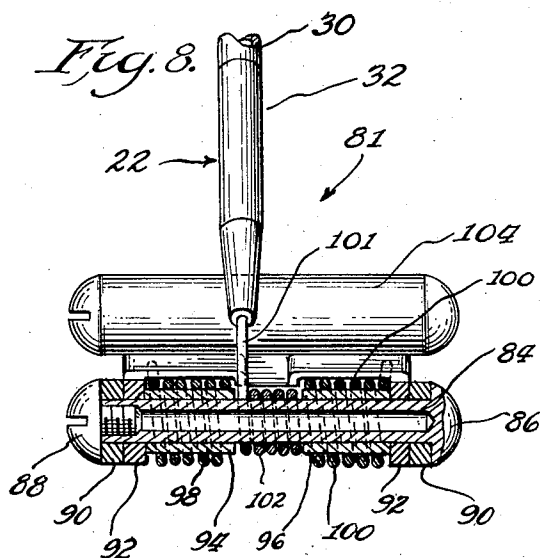
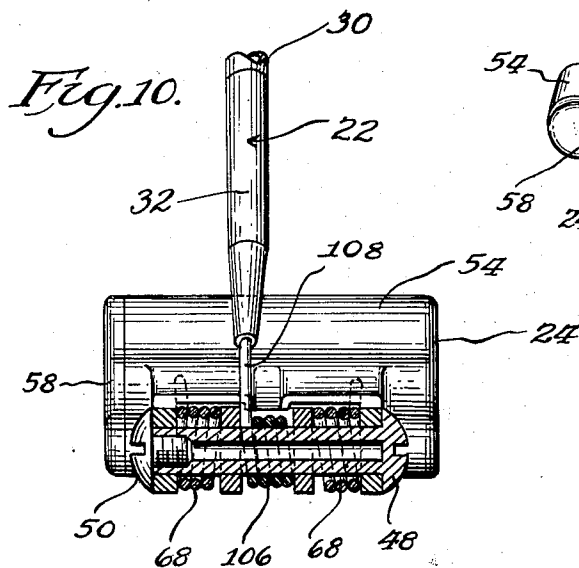
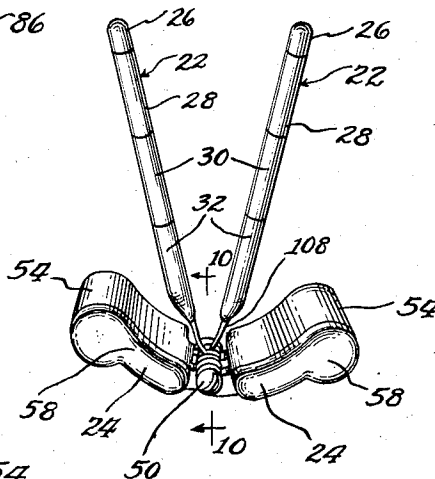


Fig. 9.



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CERVICO-VAGINAL RADIUM APPLICATOR

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Application September 8, 1954, Serial No. 454,811

9 Claims. (Cl. 128—1.2)

The present invention relates to a cervico-vaginal applicator, and more particularly to an applicator designed for the irradiation of the cervix-uteri, the paracervical and parametrial tissues, and the vaginal vault.

One of the commonest sites of cancer in women is the cervix-uteri. Numerous modes of treatment by irradiation with radium have been devised, but radium applicators of prior practices have proved to be difficult and painful to apply, and have generally failed to provide a desirable amount of homogeneous irradiation needed to objectively combat the disease. Moreover, considering the drastic nature of the treatment, applicators of prior practices do not adequately protect the normal tissues from excessive irradiation.

It is a primary object of the present invention to provide a cervico-vaginal applicator capable of more homogeneous irradiation in the uterine cavity than was heretofore possible.

Another important object of the invention is to provide a cervical-uteri applicator employing a pair of twin tandem intra-uterine stems rather than the single stem of applicators of prior practices.

A further object of the invention is to provide an applicator including a plurality of radioactive material receiving arms or stems capable of applying a greater ratio of irradiation output to the paracervical and/or parametrial tissues.

Yet another object of the invention is to provide an applicator having a pair of identical intra-uterine stems which may be positioned in substantial abutting relationship for insertion into the uterine cervix, and which upon insertion separate from each other to accurately conform to the adjacent anatomy.

Still a further object of the invention is to provide an applicator including a pair of vaginal arms which may be folded substantially together for insertion into the vaginal cavity by a pair of forceps and which automatically separate into the desired treating position adjacent the cervix upon withdrawal of the forceps.

Still a further object of the invention is to provide an applicator including a foldable pair of vaginal arms wherein a solid mass of protective metal is interposed between the radioactive sources in the applicator and the portions of the adjacent anatomy which are not diseased.

Another object of the invention is to provide an applicator including a pair of intra-uterine stems and a pair of vaginal arms arranged and disposed to collapse or fold into a relatively small bundle for insertion into position by a forceps, and which, upon release of the forceps, automatically assume correct treatment positions with respect to the diseased tissues.

According to one form of the present invention, I provide a pair of radioactive material receiving intra-uterine stems and a pair of radioactive material receiving vaginal arms pivotally connected to a common pivot pin, with the pair of stems disposed between or inwardly of the pair of arms. Resilient means urges the vaginal arms from a collapsed or folded position, wherein the outer

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ends of the arms are in contact with the respective stems, and the stems are disposed in substantially parallel abutting positions, to a spread-apart position wherein the arms diverge from said stems, and said stems diverge substantially from each other. The stems include extensions for cooperation with portions of said arms at the inner ends thereof whereby the resilient force is transferred to the stems as the arms move outwardly of each other. The arrangement is such that when the vaginal arms are gripped by a forceps to urge them toward collapsed or folded position, for insertion of the device in the vaginal cavity, the stems are respectively engaged to bring them into substantial abutting relationship whereby the stems may be inserted into the cervical os and thence into the cervical canal. Upon release of the forceps, the stems and arms are urged into a spread-apart position wherein the stems come into contact with the tissues forming the cervical canal and the arms come into contact with the cervix. Preferably, one or both of the stem extensions includes an eye or hole to which a withdrawal thread may be attached.

In another form of the invention the intra-uterine stems are secured to the upstanding ends of a helical spring wound around or received in said common pivot pin, and said extensions are omitted. In this embodiment, the resilient bias placed on the intra-uterine stems is completely independent of that placed on the vaginal arms, so that the stems will assume their body conforming configuration, once the applicator has been applied, independently of pathological or natural obstructions interfering with the desired positioning of the vaginal arms, and vice versa.

In yet another embodiment of the invention I employ the common pivot pin as a receptacle for radioactive material. This allows a radioactive source to be placed immediately adjacent the cervical os, something which was not possible in applicators of prior practices.

It will be appreciated that the present invention provides substantial advantages over applicators of prior practices. For instance, the mechanical construction is such that the applicator automatically conforms itself to the configuration of the anatomy adjacent which it is positioned and provides for a more effective irradiation of the diseased tissues. Moreover, the V or wedge shape that the stems assume with respect to each other serves to resist expulsion from the uterus and to anchor the vaginal arms adjacent the fornices.

In addition to the foregoing, it is an object of the present invention to provide an applicator of the type described which is economical of manufacture, convenient and safe in use, and readily adapted to aid in the treatment of a wide variety of cancer manifestations.

Other objects and advantages of the present invention will become apparent in the following description of preferred embodiments of the applicator of the present invention, and the preferred use thereof.

Now, in order to acquaint those skilled in the art with the applicator of the present invention and with a preferred use thereof, I shall describe, in connection with the accompanying drawings, several preferred embodiments thereof.

In the drawings:

Figure 1 is a sectional view through the pertinent portion of the female anatomy showing a preferred form of the applicator in position during treatment;

Figure 2 is a sectional view through the applicator of Figure 1, looking from the rear of Figure 1, and is seen along the line 2—2 of Figure 3;

Figure 3 is a bottom view of the applicator shown in Figure 2, partially in section;

Figure 4 is a partially exploded perspective view of the applicator of Figure 1;

Figure 5 is a perspective view of the applicator of Figure 1 taken from another position, more particularly illustrating the novel common connecting and biasing means;

Figure 6 is a perspective view of the applicator of Figure 1 gripped by a suitable form of forceps for inserting same;

Figure 7 is a perspective view of another embodiment of applicator;

Figure 8 is a sectional view along line 8—8 of Figure 7;

Figure 9 is a perspective view of still another form of applicator according to the present invention; and

Figure 10 is a sectional view along line 10—10 of Figure 9.

Referring now more particularly to Figure 1, reference numeral 10 generally indicates a preferred form of the invention in position for treatment. Diagrammatically illustrated at 12 is the vaginal cavity, the fornices at 14, the cervix at 16 (shown largely replaced by cancer tissue), the cervical canal at 18, and the body of the uterus at 20.

The applicator 10 comprises generally a pair of identical twin tandem intra-uterine stems 22 and a pair of identical vaginal arms 24. As shown in Figure 2, the stems 22 each comprise a plurality of hollow screw-threaded segments or sections 26, 28, 30 and 32, with the segments 32 merging into integral extensions 40. The segments are adapted to receive the radioactive material used in the treatment of the cervix-uteri, usually in the form of needles containing radium. The integral extensions 40 are formed with an inner loop 42 and outwardly extending ends 44; the inner loops 42 receive the pin 48 having an internally screw-threaded hole at one end thereof to receive the screw 50 (see Figures 2, 4 and 5 for the best illustration of this structure). Outwardly extending ends 44 may be pierced at 45 for insertion of a withdrawal thread, as will hereinafter be made clear. The vaginal arms 24 each are formed out of solid blocks of a suitable metal and comprise generally uniform necks 52 having ovoid shaped ends 54. Each of the arms 24 is formed with a plurality of spaced-apart compartments 56 adapted to receive the radioactive material employed to treat the cervix and vaginal fornices. Each arm 24 includes a solid plate or cap 58 held in place by countersunk screws 60 passing through suitable holes 62 in the caps and into screw-threaded holes 64 in the arms. The arms 24 are further formed with pierced lugs or loops 66 and 66a, respectively (see Figure 5), adapted to receive the pin 48, and positioned between the respective loops are a pair of springs 69 which urge the arms 24 outwardly of each other. The arms are formed with engaging surfaces or abutments 70 on the bottoms thereof which contact each other as shown in Figure 3 to preclude further movement of the arms 24 with respect to each other. Each engaging surface or abutment is slotted at 72 as shown in Figures 3 and 5 to receive an extension 40 of stems 22. It will be appreciated that as the arms 24 move outwardly of each other under the action of the springs 68, the surfaces or abutments 70 will engage the respective extensions 40 to pivot the stems about pin 48 to separate the stems from each other. The undersurfaces of the arms 24 are notched or recessed as at 74 to receive the working ends of a forceps generally indicated at 76 in Figure 6.

In use, the stems 22 and the arms 24 are supplied with the requisite amount of radioactive material needed to treat a particular patient, and the applicator is gripped by the forceps 76. It will be noted that the applicator is then in its collapsed or folded position wherein the stems 22 are in substantially parallel abutting relationship, and the arms 24 engage the respective stems 24. The applicator is then inserted through the vaginal cavity, with the intra-uterine stems 22 being passed through the cervical os into the cervical canal. The forceps 76 is then withdrawn, and the springs 68 urge the stems 22 and the arms 24 to the spread-out position substantially as shown in Figure 1, depending, of course, on the spacing of the

anatomical structures due to natural or pathological causes. Before insertion, a withdrawal thread 78 is passed through the holes 45 to aid in withdrawing of the applicator after the period of treatment has expired.

It will be appreciated that the twin stems 22, upon release of the forceps, will engage the two sides of the cervical canal and provide two radioactive sources in this area. Each half of the cervical canal is thus effectively and homogeneously exposed to radiation. The arms 24 will automatically come into close contact with the outer surface of the cervix and the vaginal fornices under the action of the springs 68; the upper surfaces of the arms 24 as shown in Figure 1 generally approximates the normal configuration of the cervix. The shape of the arms 24 is particularly helpful in insuring that the fornices will receive proper treatment, as will be immediately obvious from Figure 1.

In the illustrated embodiment, the fixed spread at the tips of the stems is preferably approximately three centimeters, tapering convergently approximately to contact at the cervical os when the applicator is in treatment position. The applicator thus conforms substantially in outline to the lateral walls of the uterine cavity. As the sources of radioactivity in the stems and in the arms 24 are relatively close together, a greater ratio of the irradiation output than was possible in prior applicators is delivered to the paracervical area. This is because the radioactive material containing portion of each stem 22 is necessarily closer to the radioactive material containing portions of the arm 24 immediately adjacent it than, for instance, the radioactive source of a single stem of applicators of prior practices could be to the radioactive sources of either arm. Moreover, the distance between the radioactive sources in the stems 22 and the arms 24, that is the interior of stems 22 and the compartments 56, is fixed once the arms 24 have been released by the forceps, whether or not the stems 24 fail to separate from each other or move outwardly of each other the full three centimeters referred to above. This is because the movement of the arms 24 outwardly of each other, after the arms 24 are released from the forceps, is controlled by and is dependent upon movement of the extensions 40 (up to the point where the abutments 70 engage each other) since arms 24 bear against said extensions under the action of springs 68. Therefore, as the stems 22 separate on withdrawal of forceps 76, the arms 24 separate the same amount; in effect the stem and arm of each side of the applicator move together as the stems separate.

For example, when the applicator 10 is positioned as shown in Figure 1 with the stems 22 together as shown in Figure 6, but with the arms 24 released to move as far as they can with respect to each other and with respect to the stems 22, there will be a space between the abutments 70 when the arms 24 have moved as far apart as possible under the tension of the springs without causing separation of the stems; this is because the extensions 40 hold the abutments 70 away from each other, the extensions 40 as shown in Figure 3 then being aligned in the vertical axis of the figure. As the stems 22 separate under the action of the springs through the arms 24 the abutments 70 move toward each other and the extensions 40 move into the respective slots 72. The movement of the arms 24 with respect to each other is therefore controlled by the spacing between stems 22, and the distance between the respective arms 24 and stems 22 is fixed regardless of the gap or spacing between the stems 22.

Another feature of the applicator which is of importance is that the V or wedge shape of the twin stems 22, when allowed to separate, serves to resist expulsion of the stems from the uterus, and also serves to anchor the vaginal arms 24 in and against the fornices. As the applicator is withdrawn by use of the thread 78, the ends 44 will be urged together, thereby urging the stems 22 together against the action of the springs 68 to allow

smooth withdrawal of the stems from the cervix with a minimum of patient discomfort. The stems 22 are of a reduced diameter at 80 (see Figure 2), the portion thereof adjacent the cervical os, to minimize dilation and the possibility of tissue injury.

A further improved feature of the applicator is the construction of the vaginal arms 24. In conventional applicators the vaginal arms have consisted of relatively thin walled capsules arranged in parallel with uniform open places separating the capsules or with a single large capsule of ovoid shape at the outer extremity of each arm. In the past, irradiation protection of adjacent normal structures has been dependent upon separating these normal anatomical structures from the sources of radioactivity by bulky gauze packing. In the present applicator, the vaginal arms are essentially solid blocks of metal, and the radioactive sources are housed in the compartment or compartments adjacent the affected tissues. Thus, the radioactive material may be placed in the compartments which will be positioned closely adjacent the affected tissues, and the normal tissues spaced from these compartments will be separated from the radioactive material by the solid mass of metal interposed between them and the filled or partially filled compartments.

The applicator is designed for use of the accepted standards of radioactive sources with the conventional 0.5 millimeter of platinum (beta ray) filtration, and for the variable placement of such sources in single, tandem or team arrangement for general or localized irradiation. The applicator therefore is readily adapted for use in practicing either the ovoid or multiple source techniques now commonly employed in treatment for cancer of the cervix. Thus, the compartments 56 at the ends of arms 24 may alone be used in practicing the ovoid technique, or all compartments 56 may be employed in practicing the multiple source technique. The sections 28, 30 and 32 forming the twin stems 22 are preferably of a length sufficient to house the standard length of radium needle (20 millimeters) and preferably the stems 22 are sufficiently long to extend to the fundus of the cervical canal. The stems 22 may be made up of more or less sections or segments than illustrated to adapt the applicator to a particular patient's needs.

The mechanical construction of the applicator is such that locking of the intra-uterine stems 22 or the vaginal arms 25 in either the open or closed position is impossible, and the applicator as a unit is smooth and rounded in shape and contour conforming substantially to the normal anatomy for patient comfort. The construction of the applicator also simplifies the readying of the applicator for use and the operative procedures for insertion and reduces irradiation exposure. Assembly and disassembly of the applicator involves only the removal of the pin 48, and the compartments containing the radioactive substances are closed by a solid face plate or cap 58 rather than a separate cap for each radioactive material container, as has been the case in applicators of prior practices.

Figures 7 and 8 illustrate a modified form of applicator 81 wherein the action of the intra-uterine stems and the vaginal arms is independent of each other, and a source of radioactivity is disposed immediately adjacent the cervical os. The modified form of applicator includes the twin tandem intra-uterine stems 22 and the modified vaginal arms 82. As shown more particularly in Figure 8, the common pivotal pin comprises an elongate tube 84 having an enlarged head 86 at one end thereof and which is internally screw-threaded at the other end thereof to receive the screw 88. The tube 84 is sufficiently large so that a source of radioactivity, such as a radium needle, may be disposed therein. The pierced lugs or loops 90 and 92 of the respective vaginal arms 82 receive the tube 84 to pivotally mount the vaginal arms on the tube. Also received on the tube 84 are a

pair of spaced sleeves 94 and 96 carrying helical springs 98 and 100, respectively, and the helical spring 102. The springs 98 and 100 act to bias the arms 84 away from each other in the same manner described in connection with the vaginal arms 24 of Figures 1 to 6, and the sleeves 94 and 96 position the spring 102 at the center of the tube 84. In this embodiment, the intra-uterine stems are mounted on the upstanding ends 101 of the helical spring 102, as shown more particularly in Figure 8. The vaginal arms 82 carry at the ends thereof receptacles 104 in which sources of radioactivity may be disposed as required. The undersurfaces of the arm 82 are notched or recessed similar to the recesses 74 illustrated in Figure 5 so that the applicator may be grasped by a forceps similar to that shown in Figure 6.

The applicator 81 of Figures 7 and 8 is inserted in the same manner as applicator 10. Upon release, however, the vaginal arms 82 and the stems 22 act independently of each other in conforming to the outline of the anatomy adjacent to which they are disposed, so that if pathological or normal body structures interfere with the normal positioning of, for instance, the arms 82, the stems 22 will still separate to conform to the outline of the cervical canal, and vice versa. Also, in cases where a recess or cavity has formed in the wall of the anatomy defining the cervical canal, and one of the stems is disposed adjacent the recess or cavity, the helical spring will urge said stem within the recess or cavity independently of the positioning of the vaginal arms 82. A withdrawal thread, if so desired, may be attached in any suitable manner to aid in withdrawing the applicator from the vaginal canal.

Figures 9 and 10 illustrate a further form of applicator wherein the stems 22, arms 24, common pivot pin 48 with screw 50, and springs 68 of Figures 1 to 6 are employed. In this embodiment, however, a helical spring 106, similar to spring 102 of Figures 7 and 8, is received on the pin 48, and the stems 22 are mounted on the upstanding ends 108 thereof. It will be appreciated that this embodiment functions similarly to that of Figures 7 and 8, employing, however, the multiple source arms 24 of Figures 1 to 6.

I comprehend that the various elements illustrated and described in connection with the three disclosed embodiments of the invention may be interchanged with slight modification, if necessary, of the other elements making up the particular embodiment. For instance, the hollow radioactive material receiving tube 84 of Figures 7 and 8 could be used in connection with the embodiments illustrated in Figures 1 to 6 and Figures 9 and 10. Moreover, the movement of the stems 22 of the embodiments of Figures 7 to 10 may be controlled by the movement of the vaginal arms in the manner described in connection with the embodiment shown in Figures 1 to 6.

The various described embodiments may be made from any suitable metals, such as brass, stainless steel, Monel metal, copper, or the like.

The foregoing description and the drawings are given merely to explain and illustrate my invention, and the invention is not to be limited thereto, except insofar as the appended claims are so limited since those skilled in the art who have my disclosure before them will be able to make modifications and variations therein without departing from the scope of the invention.

I claim:

1. A cervico-vaginal radium applicator comprising, a pair of intra-uterine stems pivotally connected together adjacent a like end of each for movement between a contracted position wherein they are in substantially side-by-side and aligned relation and a spaced apart position wherein they are in spread apart substantially V-shaped relation, a pair of vaginal arms pivotally connected together adjacent a like end of each and positioned on either side of said stems, said arms being pivotally connected for movement between a contracted position wherein the

free ends of said arms respectively abut said stems and a spaced apart position wherein said free ends are both spaced from the said stems, with the pivotal connection of said arms being positioned adjacent the pivotal connection of said stems, and means for biasing said stems and said arms to their respective spaced apart positions, said arms each being formed with radium receiving compartments and said stems comprising radium receiving compartments, whereby, said stems and said arms when clamped in said contracted positions may be inserted through the vaginal cavity and said stems passed through the cervical os into the cervical canal, and when unclamped, said means urges said stems and said arms into said spaced apart positions wherein said stems engage opposite sides of the cervical canal and said arms engage the outer surface of the cervix.

2. A cervico-vaginal radium applicator, comprising a pair of intra-uterine stems pivotally connected together adjacent a like end of each for movement between a contracted position wherein they are in substantially side-by-side and aligned relation and a spaced apart position wherein they are in spread apart substantially V-shaped relation, a pair of vaginal arms pivotally connected together adjacent a like end of each and positioned on either side of said stems, said arms being pivotally connected for movement between a contracted position wherein the free ends of said arms respectively abut said stems and a spaced apart position wherein said free ends of said arms are both spaced from said stems, common pin means effecting said pivotal connections of said stems and said arms, and spring means for biasing said stems and said arms to their respective spaced apart positions, said arms each being formed with radium receiving compartments and said stems comprising radium receiving compartments, whereby, said stems and said arms when clamped in said contracted positions may be inserted through the vaginal cavity and said stems passed through the cervical os into the cervical canal, and when unclamped, said spring means urges said stems and said arms into said spaced apart positions wherein said stems engage opposite sides of the cervical canal and said arms engage the outer surface of the cervix.

3. The applicator set forth in claim 1 wherein said spring means comprises spring means acting only on said vaginal arms, said like ends of said stems including extensions for cooperating with said like ends of said arms to urge said stems into said spaced apart position.

4. The applicator set forth in claim 1 wherein said spring means comprises separate spring means acting on said arms and said stems, respectively.

5. The applicator set forth in claim 1 wherein said pin means is formed to define a radium receiving compartment.

6. The applicator set forth in claim 1 wherein said vaginal arms each further comprise an elongate body of metal formed with a plurality of spaced compartments.

7. A cervico-vaginal radium applicator comprising a pair of elongated, relatively thin intra-uterine stems pivotally connected together adjacent a like end of each for movement between a contracted position wherein they are in substantially side-by-side and aligned relation and a spaced apart position wherein they are in spread apart substantially V-shaped relation, pin means effecting said

pivotal connection between said stems, spring means for biasing said stems to their respective spaced apart positions, said stems comprising radium receiving compartments, and radium receiving compartment means secured to said pin means, said compartment means being larger than the cross sectional dimension of said stems when in said contracted position, whereby, said stems when clamped in said contracted position may be inserted through the vaginal cavity and passed through the cervical os into the cervical canal, and when unclamped, said spring means urges said stems into said spaced apart position wherein said stems engage opposite sides of the cervical canal and draw said radium receiving compartment means against the cervix.

8. A cervico-vaginal applicator comprising a pair of vaginal arms pivotally connected together adjacent a like end of each, pin means effecting said pivotal connection of said arms, said arms being pivotally connected for movement between a contracted position wherein the free ends of said arms are positioned adjacent each other and a spread apart position wherein said free ends of said arms extend away from each other, said arms each being formed out of a solid length of metal and each length of metal being formed with a plurality of radium receiving compartments that extend parallel to said pin means, said lengths of metal being, transversely of the axis of said pin means and between said like ends and said free ends of the respective arms, of a thickness greater than the transverse dimension of said compartments, and intra-uterine stem means secured to said pin means, whereby, said arms, when clamped in said contracted position, and said stem means may be inserted through the vaginal cavity and said stem means passed through the cervical os into the cervical canal, and when said arms are released, said spring means urges said arms into said spaced apart position wherein said arms engage the outer surface of the cervix.

9. The applicator set forth in claim 8 wherein said compartments each include an open end and a closed end, said open ends of said compartments all being formed in the same side of the respective arms, and including a single cover plate for each arm that is proportioned to close the open ends of all compartments in the arm, and means for securing said cover plates to the respective arms.

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