

June 6, 1967

J. W. HOLTER

3,323,511

RADIATION SOURCE APPLICATOR

Filed March 5, 1962

3 Sheets-Sheet 1

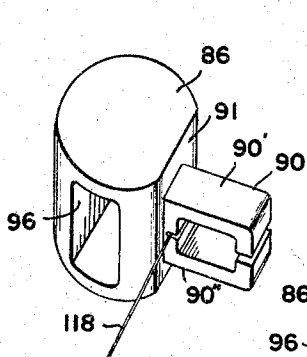


FIG. 4.

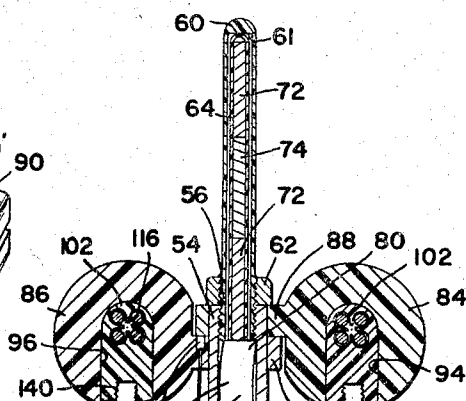


FIG. 1.

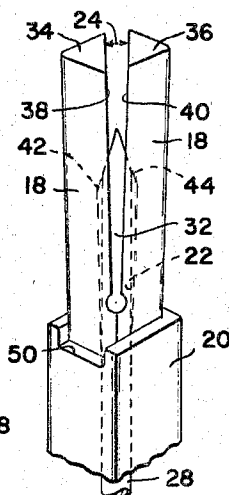


FIG. 2.

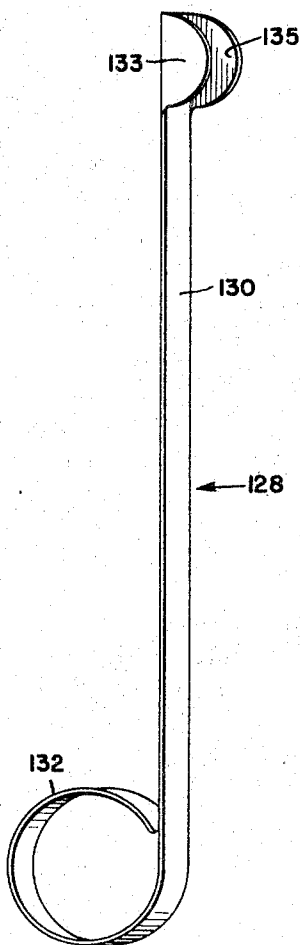


FIG. 7.

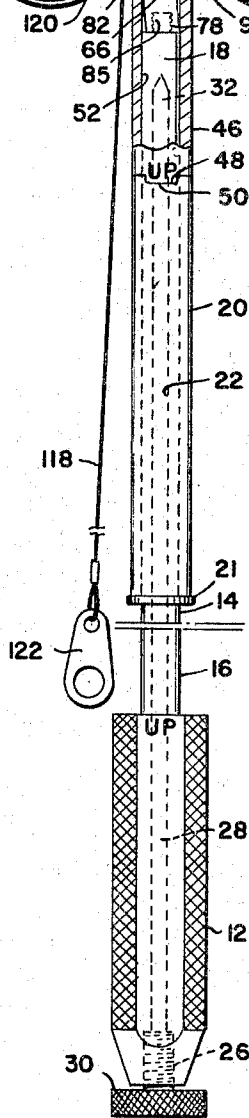


FIG. 8.

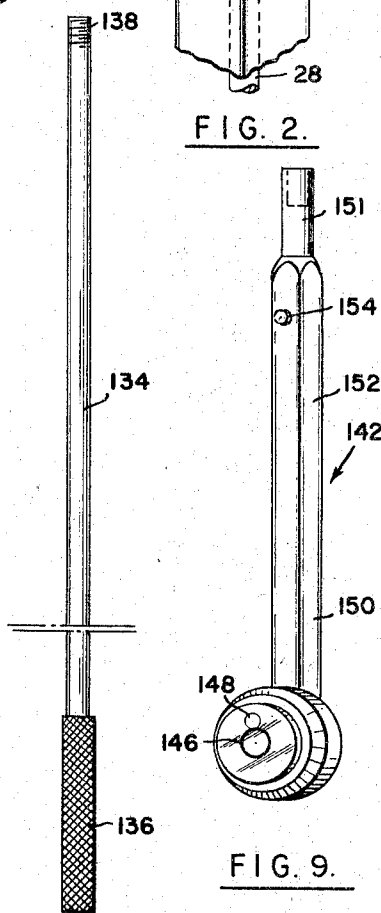


FIG. 9.

INVENTOR.

JOHN W. HOLTER

BY

Besser, Smith & Hardy
ATTORNEYS

June 6, 1967

J. W. HOLTER

3,323,511

RADIATION SOURCE APPLICATOR

Filed March 5, 1962

3 Sheets-Sheet 2

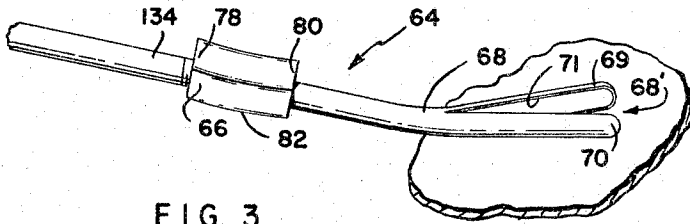


FIG. 3.

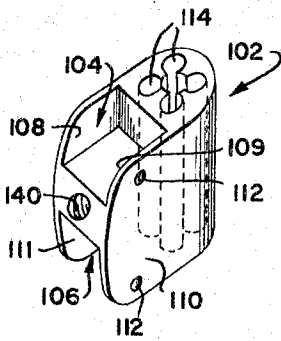


FIG. 5.

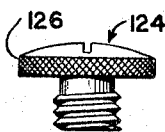


FIG. 6.

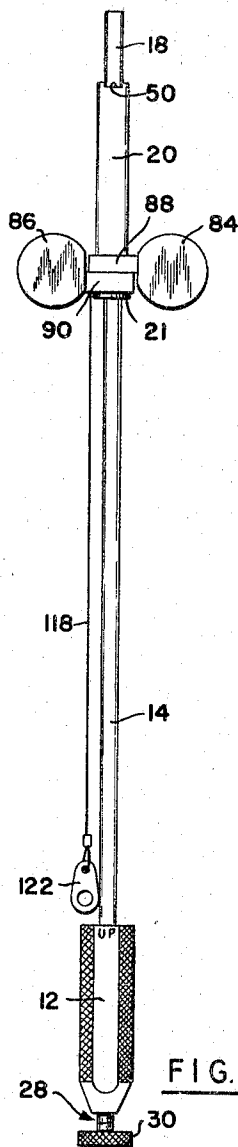


FIG. 10.

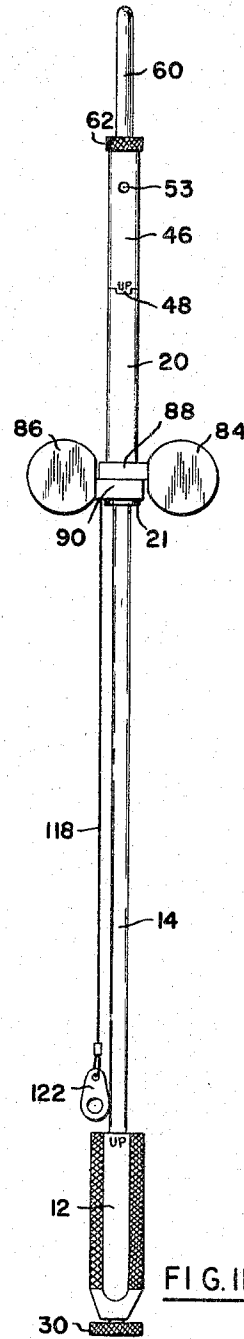


FIG. 11.

INVENTOR.

JOHN W. HOLTER

BY

Bruce Smith & Harkley
ATTORNEYS

June 6, 1967

J. W. HOLTER

3,323,511

RADIATION SOURCE APPLICATOR

Filed March 5, 1962

3 Sheets-Sheet 3

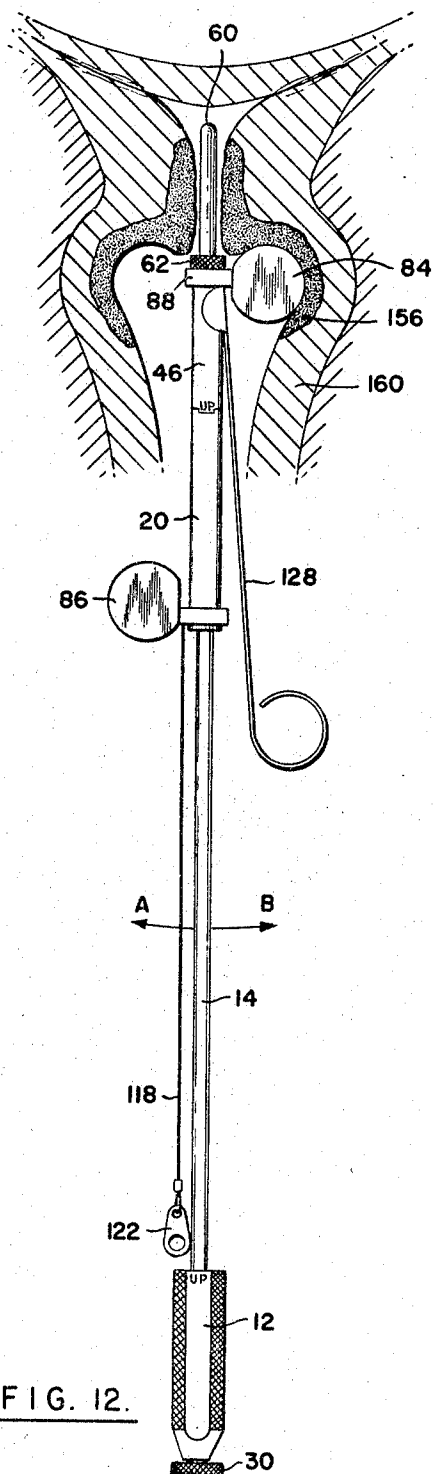


FIG. 12.

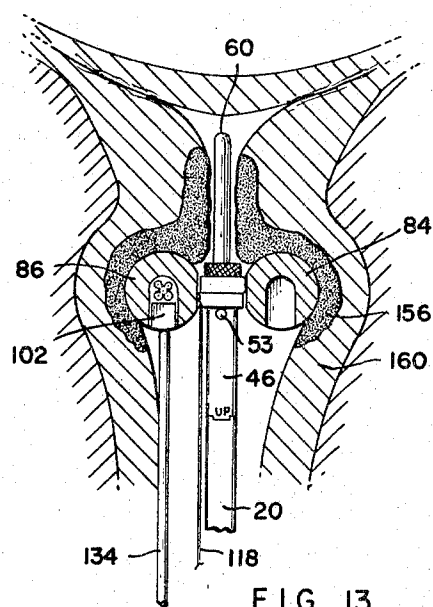


FIG. 13.

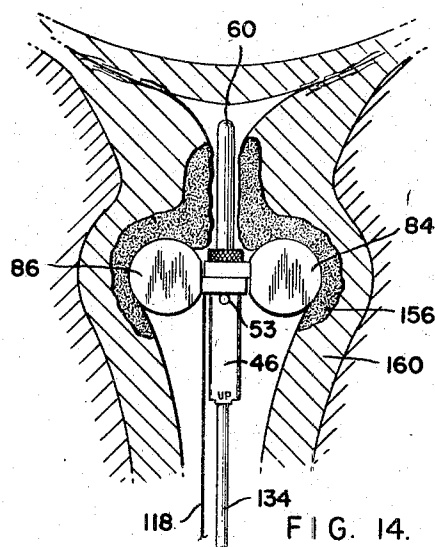


FIG. 14.

INVENTOR.

JOHN W. HOLTER

BY

51
Benson, Smith & Harding

ATTORNEYS

1

3,323,511

RADIATION SOURCE APPLICATOR

John W. Holter, Gulph Mills, Pa., assignor to The Holter Company, Bridgeport, Pa., a corporation of Pennsylvania

Filed Mar. 5, 1962, Ser. No. 177,539

3 Claims. (Cl. 128-1.2)

This invention relates to a medical instrument for inserting into and withdrawing from the human anatomy radioactive materials which are used in the treatment of cancerous growths. More particularly, this invention is concerned with an applicator which greatly facilitates the insertion and particularly the withdrawal of such radioactive materials from the interior portions of female reproductive organs wherein a disproportionately large percentage of cancerous growths occur and wherein the radioactive treatment is complicated by the internal location, the particular shape, and the wide range of variations in the size of such organs.

Heretofore, various radium applicators have been designed for use in treating cancerous growths occurring in the vaginal, cervix and uterine canal regions. However, these instruments have not proved to be entirely satisfactory due to the particular problems set forth hereinabove. For example, the interior location at which the growth occurs necessitates the passage of the radiation source through and along extended portions of adjacent organs which do not contain cancerous growths and which should not be exposed to any radiation other than that which is absolutely necessary. Secondly, the particular shape of the immediately adjacent portions of the organs in the vicinity of the cervix requires the applicator to be basically in the form of an inverted T, whereas, the organs through which the applicator must pass when being inserted or withdrawn do not readily conform to such a configuration. For this reason some applicators of the previously known types have included relatively complex adjusting mechanisms whereby the arms of the T are folded or shortened during the insertion and removal. This is objectionable in that such mechanisms are susceptible of becoming inoperative due to the entry of body fluids and/or blood into the somewhat complex system of levers, gears and racks comprising the adjusting mechanism while it is within the patient during the period of treatment. Thus, removal sometimes involves major surgery which is obviously to be avoided because this type of patient is generally a poor surgical risk.

A further disadvantage of previously known applicators resides in the fact that, heretofore, the portion of the applicator which is to remain within the patient during the treatment period had to be filled with the radioactive material prior to the insertion thereof into the patient. The presence of the radioactive material is undesirable when the device is being inserted as during manipulation, the operator would be unduly exposed to accumulative and dangerous radiation.

It is therefore an object of the invention to provide an applicator wherein various sized ovoids are provided and wherein each ovoid is an independent unit which may be individually inserted and later withdrawn without mechanical adjustment of its size or shape.

A further object of the invention is to provide an applicator which may be filled with the radiation source after it has been inserted into the patient and precisely positioned therein, thereby, eliminating the danger of radioactive exposure to both the operator and patient.

The attainment of the foregoing and other objects of the invention, particularly those relating to the details of construction as well as the preferred method of use, will become more fully apparent from the following descrip-

2

tion when read in conjunction with the accompanying drawings, in which:

FIGURE 1 is an elevational view, partly in section, showing the applicator in its assembled condition;

FIGURE 2 is an enlarged, perspective view of the shank portion of the applicator;

FIGURE 3 is an enlarged perspective view of the uterine stem carrier portion of the applicator;

FIGURE 4 is an enlarged, perspective view of the ovoid portion of the applicator;

FIGURE 5 is an enlarged, perspective view of the ovoid carrier portion of the applicator;

FIGURE 6 is an elevational view of a protective plug used with the applicator;

FIGURE 7 is a perspective view of a push rod used with the applicator;

FIGURE 8 is an elevational view of an extension rod used with the applicator;

FIGURE 9 is a perspective view of a level used with the applicator;

FIGURE 10 is an elevational view of the applicator in a first partially assembled condition;

FIGURE 11 is an elevational view of the applicator in a second partially assembled condition;

FIGURE 12 is an elevational view of the applicator in a first operative condition within the patient;

FIGURE 13 is an elevational view of the applicator in a second operative condition within the patient; and

FIGURE 14 is an elevational view of the applicator in a third operative condition within the patient.

In FIGURE 1 applicator 10 is shown in its fully assembled condition wherein it includes a handle portion 12 rigidly connected to a shank portion 14 having a substantially square cross-section throughout its length. Shank 14 includes a lower portion 16 and an upper portion 18 which are of substantially the same width as well as a central portion 20 having a greater width than that of portions 16 and 18. In the form of the invention illustrated in FIGURE 1, portion 20 is a separate element which is brazed, welded or otherwise rigidly secured about the lesser diametered portion of shank 14. However, it will be understood that portion 20 may be integral with portions 16 and 18. The lower end of portion 20 terminates in a flange 21 and it should be noted that all of the above-described parts are preferably composed of an acid resistant material such as stainless steel for example.

Handle 12 and shank 14 are provided with a centrally disposed bore 22 which extends from the lowermost portion of handle 12 up to the mid-section of portion 18 at which point the bore communicates with a diagonally disposed slot 24 as more clearly shown in FIGURE 2. At the lower end of handle 12, bore 22 is internally threaded for the reception of the threaded portion 26 of cam rod 28 which extends substantially the full length of bore 22. Rod 28 is also provided with a knob 30 by which rod 28 may be rotated relative to handle 12 to thereby reciprocate tip 32 within slot 24. As most clearly shown in FIGURE 2, slot 24 divides portion 18 into split halves 34 and 36 having oppositely facing surfaces 38 and 40. Bore 22 terminates in tapered grooves 42 and 44 which are located in surfaces 38 and 40, respectively. Therefore, as tip 32 is moved upwardly, as viewed in FIGURE 2, the conical cam portion of tip 32 engages cam grooves 42 and 44 thereby causing portions 34 and 36 to diverge slightly, whereas, retraction of tip 32 allows portions 34 and 36 to return to their parallel spaced position as shown in FIGURE 2 due to their natural resiliency.

Referring back to FIGURE 1, numeral 46 designates a substantially hollow support member which is slidably received over shank portion 18 and which has a width equal to that of portion 20. In order to prevent incorrect

alignment of member 46 relative to portion 20, member 46 is provided with a projecting tab 48 which is received in notch 50 of portion 20 when member 46 and portion 20 are in proper angular alignment. In addition, member 46 and handle 12 are each provided with suitable markings such as the word "up" in order to provide a second means of insuring proper alignment of the respective parts particularly when the former is positioned within the patient as will be more fully described hereafter. In order to facilitate easy assembly and disassembly, the square bore 52 of member 46 is made slightly larger than the width of shank portion 18 which is received within it. However, when tip 32 of rod 28 is moved upwardly against cam surfaces 42 and 44, as previously described, portions 34 and 36 diverge and bear against the internal surfaces of bore 52 whereby member 46 is frictionally engaged and securely held in the assembled condition shown in FIGURE 1. On the other hand, retraction of tip 32 permits portions 34 and 36 to return to their parallel positions and thus allow easy withdrawal of portion 18 from within member 46.

Member 46 is further provided with a threaded portion 54 into which threaded portion 56 of hollow stem 60 may be received. In order to prevent accidental separation of stem 60 from member 46, threaded portion 56 is of greater axial length than threaded portion 54 so that the former projects beyond the end of member 46 and thereby provides for the reception of a lock nut 62 which interlocks stem 60 and member 46. Stem 60 is preferably composed of an acid resistant plastic such as nylon so that it is unaffected by bodily acids with which it comes in contact. Stem 60 is provided with a closed bore 61 extending substantially throughout its entire length. Stem 60 serves as a receptacle and protective covering for a uterine source carrier 64 which is shown in FIGURES 1 and 3. Carrier 64 is preferably composed of acid resistant plastic and includes a base member 66 and an extending tubular portion 68. Tubular portion 68 is closed at one end by lip portions 69 and 70 which are separated by a slit 71 which extends for a short distance along one side of the tube and for a greater distance along the other side of the tube. As shown in FIGURE 3, slit 71 permits lips 69 and 70 to diverge when tip 68' of tubular portion 68 is pressed against a surface so that one or more radioactive slugs 72 and spacer blocks 74 may be inserted within stem 68.

As previously stated, stem 68 is composed of a plastic material and is sufficiently flexible to permit lips 69 and 70 to diverge and then converge in the above manner due to its natural resiliency. Base portion 66 has a square cross-section which is slightly smaller than that of bore 52 of member 46 wherein it is received as shown in FIGURE 1. However, base 66 is slightly curved along its longitudinal axis so that edges 78, 80 and intermediate portion 82 frictionally engage opposite internal surfaces of bore 52 and thereby prevent accidental separation of member 64 from support 46. It will also be noted that base 66 is provided with a threaded portion 85 so that an extension rod such as that shown in FIGURE 3 may be secured thereto in order to facilitate handling of radioactive source carrier 64 at a distance from the operator.

In addition to serving as a support for carrier 64, member 46 also serves as a support for the ovoids 84 and 86 which are provided with arms 88 and 90, respectively. Since ovoids 84 and 86 are substantially identical, only ovoid 86 will be described in detail with particular reference to FIGURE 4 wherein arm 90 is shown to include integral, C-shaped portions 90' and 90'' which together form a square aperture through which member 46 is slidably received when the applicator is assembled. The ovoids are also preferably composed of acid resistant and slightly flexible plastic whereby arms 90' and 90'' are capable of being forced apart slightly as they pass over raised detents 53 provided on the external surface of member 46. Due to the inherent resiliency of the plastic,

portions 90' and 90'' snap into place around member 46 after passing over the detents. Ovoids 84 and 86 are substantially cylindrical except for planar surfaces 91, 92 from which arms 88 and 90 project. The ovoids are further provided with respective cavities 94 and 96 for receiving ovoid radiation carriers 102 and 104. At this point it should be noted that ovoids 84 and 86 serve as substantially hollow containers which may be moved along portions 20 and 46 and snapped into the positions shown in FIGURE 1.

Reference is now made to FIGURE 5 wherein one of the ovoid radiation carriers 102 is shown in perspective. The carrier is also composed of acid resistant plastic material and is substantially rectangular in shape except for notches 104 and 106 which determine the thickness, and therefore the flexibility, of walls 108 through 111. Each of walls 108 through 111 is provided with a raised dimple 112 which frictionally engages the internal surface of cavity 94 when the carrier is inserted into the ovoid as shown in the assembled condition in FIGURE 1. Thus, the slight resiliency of walls 108 through 111 determine the force with which dimples 112 frictionally engage and thereby hold the carrier within the cavity. This force may be made just sufficient to retain the carrier in the ovoid while, at the same time, permitting easy manual insertion and withdrawal of the carriers. Carriers 102 are further provided with a plurality of blind bores 114 wherein the radioactive slugs 116 are inserted and a threaded bore 140 for the reception of an extension rod of the type shown in FIGURE 8.

Referring back to FIGURE 1, it will be noted that ovoids 84 and 86 are identical in construction except for the fact that arms 88 and 90 are laterally offset in opposite directions, respectively. Thus, when the ovoids are assembled on member 46 as shown in FIGURE 1, arms 88 and 90 overlie one another thereby positioning bores 114 in the same plane transverse to the longitudinal axis of shank 14. It will be further noted that ovoid 86 is provided with an elongated wire 118 the upper end of which is fastened to a plug 120 imbedded in arm 90. The opposite end of wire 118 is fastened to a tab 122 the purpose of which will hereinafter be described.

Reference may now be made to FIGURES 6 through 9 which show various auxiliary instruments employed during the insertion and removal of applicator 10. FIGURE 6 illustrates a plug 124 which may be threadedly received in threaded portion 54 of member 46 in place of stem 60 when the latter is not required for treatment of the patient. It will be noted that the cap portion 126 of plug 124 has a diameter which is equal to that of lock nut 62 so that it serves the same function of limiting the upward travel of the ovoids as does lock nut 62 when stem 60 is employed.

FIGURE 7 illustrates a push rod 128 which is composed of a flat strap member 130 having a curved handle portion 132 and a pair of laterally spaced lugs 133 and 135 which are adapted to overlie opposite sides of member 46 and central portion 20 of the applicator. Push rod 128 is employed to move the ovoids along member 46 and portion 20 as will be more fully described hereinafter.

FIGURE 8 illustrates an extension rod 134 which includes a handle portion 136 and a threaded portion 138. It will be readily understood that threaded portion 138 is of a size to fit threaded portion 85 of base member 66 as well as threaded portion 140 of carriers 102.

FIGURE 9 illustrates a spirit level 142 which includes a sealed liquid containing a bubble 148. A reference circle 146 is provided on the enclosure so that a level condition of attached rod 150 is indicated when bubble 148 is entirely within circle 146. Rod 150 terminates in a cylindrical portion 151 which is of lesser diameter than the width of the square portion 152. A stop 154 is secured to the upper end of portion 152 and serves to abut the lower edge of member 46 when the rod is

5

inserted into bore 52. The cylindrical portion 151 serves to initially guide the rod into bore 52 and, thereafter, the square portion 152 is received within bore 52 until stop 154 abuts the lower projection 48. It is to be understood that the size of portion 152 is accurately determined relative to the size of bore 52 so that there is a close sliding fit between the parts thereby insuring an accurate indication of the position of member 46.

The operational procedure for using the above-described instrument will now be set forth with particular reference to FIGURES 10 through 13. The patient is first examined and prepared using the customary treatment for dilation and curettage. A pair of ovoids such as 84 and 86 are then selected on the basis of the size of the vaginal cavity and a uterine stem such as 60 is also selected on the basis of the depth of the uterine canal. At this point, support member 46 is separate from shank 14 so that ovoids 84 and 86 may be slidably placed on portion 20 with ovoid 86 being positioned closest to handle 12. Both ovoids are then pushed axially along portion 20 so that arm 90 of ovoid 86 rests against flange 21 as shown in FIGURE 10. The previously selected uterine stem 60 is then threaded into portion 54 of support member 46 and lock nut 62 is tightened in position to prevent stem 60 from separating from member 46. Thereafter, as shown in FIGURE 11, support member 46 is slidably received on shank 14 with projection 48 being received in groove 50 to thereby insure the proper alignment of shank 14 and member 46. It should also be noted that when the parts are properly aligned, the words "up" on member 48 and handle 12 both face in the same direction. Thus, a reference position is established the purpose of which will be more clearly pointed out hereinafter. Rod 28 is then inserted in bore 22 and knob 30 is rotated so that the threads on rod 28 engage threaded portion 26 and, upon continued rotation of knob 30, tip 32 is forced upwardly and bears against tapered cam surfaces 42 and 44. This causes portions 34 and 36 to diverge slightly as previously described so that they tightly engage the interior of bore 52 and thereby lock support member 46 on the end of shank 14. The applicator is then in the partially assembled condition illustrated in FIGURE 11.

With the applicator in this condition, uterine stem 60 is inserted through the dilated cervix and positioned in the uterine canal such that lock nut 62 becomes immediately adjacent the cervical fornices. Push rod 128 is then positioned with flanges 133 and 135 on opposite sides of shank portion 20 and, while firmly grasping handle 12, ovoid 84 is pushed upwardly along portion 20 and member 46 until arm 88 has passed over detents 53 and comes into abutment with lock nut 62. The applicator is then in the position illustrated in FIGURE 12. Since each of the ovoids is moved independently along shank 14, it should be noted that the entire shank portion may be alternately displaced in the directions indicated by arrows A and B so that the entry of each of the ovoids is facilitated. After ovoid 84 has been properly positioned according to the previously described procedure, ovoid 86 is similarly pushed along portion 20 and support member 46 until it passes over detents 53 and snaps into locked position. It will be noted that arms 88 and 90 pass over detents 53 by reason of their split and flexible construction previously described with reference to FIGURE 4 and it is to be understood that although portions 90' and 90'' are slightly flexible, they are not sufficiently flexible to allow the ovoids to slide over the detents unless a manual force is applied. Thus, the ovoids remain in their locked position.

At this point it should also be noted that, since the ovoid source carriers are not present in the applicator at this time, the above procedure may be accomplished with gloved fingers and may be done slowly and carefully so that the applicator is positioned in precisely the proper location for treating the cancerous tissue 156.

After the insertion and positioning of the ovoids, ovoid carrier 102, which has been previously attached to exten-

6

sion rod 134 and loaded with radiation sources in bores 114, is then inserted into cavity 94 of ovoid 86 as shown in FIGURE 13. It is to be understood that the insertion of the carrier may be facilitated by the use of conventional retractors to displace any tissue which may tend to cover the opening of the cavity in the ovoid. Once the carrier is inserted into the ovoid, dimples 112 engage the internal surface of the cavity and securely hold the carrier in place so that insertion rod 134 may be unthreaded and withdrawn. This procedure is then repeated with regard to carrier 104 and the extension rod of that carrier is similarly removed.

After the ovoid carriers have been inserted by the above-described procedure, the ovoids may be packed in place using suitable wide gauge packing. Thereafter, knob 30 is rotated in the direction opposite to that previously described and tip 32 of rod 28 is thereby withdrawn from engagement with cam surfaces 42 and 44. This allows portions 34 and 36 to resume their parallel positions thus, releasing the frictional engagement with the internal surface of bore 52 so that the entire shaft portion of the applicator shank 14 may be completely withdrawn, leaving the support member 46 and the ovoids in place as shown in FIGURE 14.

The withdrawal of shank 14 places the interior of stem 60 in communication with bore 52 so that the previously loaded uterine stem carrier 64 may be inserted in bore 52 by means of rod 134 and pushed upwardly into stem 60 as shown in FIGURE 14. As described with reference to FIGURE 1, the slight curvature of base 66 frictionally holds the carrier within bore 52 and, due to the square cross-section of base 66, rod 134 may be threaded and withdrawn. Thus, the applicator is now fully loaded with radioactive sources and the period of radiation treatment therefore begins. However, radiographs should be obtained in order to verify the radiation pattern. For this purpose, rod 150 of spirit level 142 is inserted in bore 52 and the position of the patient is then precisely adjusted on the radiograph table so that accurate radiographs may be obtained.

After the lapse of the prescribed treatment period, the applicator may be readily removed by the following procedure. First, rod 134 is inserted in bore 52 and tip 138 is threadedly received in bore 85 of uterine stem carrier 64. By grasping handle 136 the carrier is then withdrawn from within stem 60. The packing is then removed and shank 14 is inserted with the word "up" facing the operator whereby proper alignment is insured. Knob 30 is rotated in order to expand portions 34 and 36 so that shank 14 is again rigidly connected to support member 46. By grasping handle 12 and tab 122, ovoid 86 is pulled downwardly along member 46 and portion 20 until it is completely withdrawn from the patient. As noted in the insertion procedure, this may be facilitated by moving the handle in the direction of arrows A and B shown in FIGURE 12. Once ovoid 86 is fully removed, the remaining ovoid 84 may be withdrawn along with stem 60 and the entire applicator structure as a unit. Since the ovoids still contain the radioactive sources, these may be then withdrawn and placed in suitable shielded containers.

From the foregoing description it will be apparent that the invention provides for the rapid and accurate insertion and withdrawal of the apparatus without requiring any complicated adjusting mechanism which may become inoperative. The invention is therefore made considerably safer and easier to use than has been possible with previously known applicators. In addition, the invention provides for the loading of the applicator with the radioactive sources after the insertion and proper positioning of the applicator rather than prior to the insertion.

Since numerous modifications of the above-described structure and procedure will be readily apparent to those skilled in the art, it is to be understood that the foregoing description pertains only to a preferred embodiment and

7

that the invention is not to be limited otherwise than as set forth in the following claims.

What is claimed is:

1. A radiation source applicator for treating diseased portions of the uterine and cervico-vaginal organs comprising,
 - a support member,
 - a pair of individual ovoids mounted on said support member for independent movement,
 - a uterine stem removably secured to said support member,
 - each of said ovoids and said stem having a cavity opening to the interior thereof,
 - a pair of radiation source carriers contained within the cavities in said ovoids,
 - a third carrier contained within the cavity in said stem, said third carrier being in the form of a closed cylinder of flexible material and having a slit along a portion of its length,
 - an elongated member removably secured to said support member of positioning the latter in the vicinity of the cervico-vaginal organs, and
 - means for individually moving said ovoids into positions immediately adjacent said organs.
2. A radiation source applicator for treating diseased internal organs comprising,
 - a plurality of individual containers for containing radiation sources,
 - a first shaft,
 - a second shaft,
 - means for releaseably coupling one end of said second shaft to one end of said first shaft,
 - means individually mounting each of said containers for sliding movement along the lengths of said first and second shafts, and
 - means for releaseably maintaining said containers in

8

a predetermined position along the length of said first shaft.

3. A radiation source applicator for treating diseased internal organs comprising,
 - a plurality of individual containers for containing radiation sources,
 - a first shaft having a central bore opening to one end thereof,
 - a second shaft having a portion of a size to fit within said bore,
 - means for releaseably securing said shaft portion within said bore,
 - means individually mounting each of said containers for movement along the lengths of said first and second shafts, and
 - means for releaseably maintaining said containers in a predetermined position along the length of said first shaft.

References Cited

UNITED STATES PATENTS

1,525,158	2/1925	Viol	128—1.2
1,603,767	10/1926	Harris	128—1.1
2,516,261	7/1950	Schutt	128—1.2
2,829,636	4/1958	Henschke	128—1.2
2,888,917	6/1959	Fordyce	128—1.2
3,060,924	10/1962	Rush	128—1.2

FOREIGN PATENTS

3,717	12/1904	France.
		(Addition to 344,809)
750,422	5/1933	France.
1,150,752	8/1957	France.
875,997	5/1953	Germany.

RICHARD A. GAUDET, *Primary Examiner*.

W. E. KAMM, *Assistant Examiner*.