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(72) Inventor; and
(71) Applicant: SMIT, Berend, Jakobus [ZA/ZA]; 62 J S Marais Street, Kleinmond, Western Cape Province (ZA).

(74) Agent: VON SEIDELS; P O BOX 440, Century City, (Cape Town), 7446 (ZA).


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CERVICAL RADIATION THERAPY SLEEVE

FIELD OF THE INVENTION

This invention relates to a cervical radiation therapy sleeve or tube for containing a radiation emitting treatment medium for use in the radiation therapy or, as it is often referred to as brachytherapy, of cervical cancer.

BACKGROUND TO THE INVENTION

The use of an indwelling intrauterine sleeve that operatively extends through the cervix and into the uterus is often a preferred treatment procedure for cervical cancer depending on the type and stage of development of the relevant cancer. The radiation emitting treatment medium contained within the sleeve may be selected to provide short or long term radiation therapy and is typically selected from HDR iridium-192 and LDR radium. Of course, any other suitable treatment medium may be carried in the sleeve.

Existing sleeves typically have a flange at the operatively outer end with holes through the flange for receiving stitches in the event that such an attachment method is considered to be appropriate. However, it is preferred in many instances not to use stitches and in such an instance it is possible that the sleeve may move outwards, on its own, from its desired operative position. It is to be noted that the commercially available sleeves known to applicant have a smooth substantially constant diameter outer surface.

Early proposals did suggest the use of one or more spaced ridges encircling the outer surface of the sleeve wherein the ridges were of a squat saw-tooth shape in longitudinal section so that insertion was facilitated and movement out of the operative position was inhibited. However such an arrangement,
applicant believes, interfered with desired removal at the end of a session of treatment and may have resulted in injury to the patient, or at least undesirable irritation of the cervix.

OBJECT OF THE INVENTION

It is an object of this invention to provide a cervical radiation therapy sleeve that has enhanced features contributing to retention of such a sleeve in its operative position without the necessity of employing stitches.

SUMMARY OF THE INVENTION

In accordance with this invention there is provided a cervical radiation therapy sleeve comprising a tube suitable for containing radiation emitting therapy medium, a flange at an operatively outer end thereof, and an operatively inner end, the sleeve having a length selected such that it extends operatively through the cervix of a patient to terminate in the uterus, the radiation therapy sleeve being characterized in that the sleeve has, towards its inner end, at least two generally radially extending flexible barb formations arranged symmetrically about the axis of the sleeve and having remote free ends spaced from the outer sleeve surface by a distance providing for co-operation thereof with the uterus wall to at least partially support the weight of the sleeve in the uterus and inhibit natural movement of the therapy sleeve out of its operative position but to flex towards the sleeve to permit clinical introduction and removal of the sleeve.

Further features of the invention provide for a central region of the length of the sleeve to have a slightly enlarged outer diameter providing a bulge in a central region thereof that is adapted to further inhibit natural movement of the sleeve from its operative position; for the radiation therapy sleeve to be made of an injection moulded plastics material that is preferably flexible and most preferably elastomeric; for there to be two, three, four, five or six barbs
arranged symmetrically about the axis of the sleeve; for the barbs to be either of circular shape in cross-section or, preferably, elongate rectangular shape in cross-section with the longer dimension of the rectangle extending in a generally circumferential direction relative to the axis of the sleeve; and for the barbs to extend somewhat at an incline to the radial direction so that they are angled somewhat towards the flange end of the sleeve.

As a general rule, the outer diameter of the sleeve is about 5 or 6 mm; the outer diameter of any bulge in a central region of the sleeve is typically about 1 mm greater than the outer diameter of the sleeve itself, or somewhat larger; the diameter of the flange is typically about 15 mm; and the diameter of a circle encircling the outer extremities of the barbs would typically be about the same as the diameter of the flange, but may be somewhat less. The length of the sleeve may vary, as will be apparent to those skilled in the art, and is typically from about 50 mm to about 70 mm.

As for the barbs themselves, they will preferably have a thickness in the direction of the axis of the sleeve of from 0.5 to about 1.0 mm and a dimension in the circumferential direction of about 1 to 2 mm.

The sleeve itself may have a closed inner end in which instance it will preferably have radially extending drainage holes, or it may have an open inner end in which instance drainage holes are rendered unnecessary.

In order that the invention may be more fully understood, various embodiments thereof will now be described with reference to the accompanying drawings.
In the drawings:—

Figure 1 is an isometric view of a first embodiment of the invention;

Figure 2 is an isometric view of a second embodiment of the invention;

Figure 3 is an isometric view of a third embodiment of the invention;

Figure 4 is an isometric view of a fourth embodiment of the invention; and,

Figure 5 is a schematic illustration of the second embodiment of the invention in an operative position.

In the first embodiment of the invention illustrated in Figure 1, a cervical radiation therapy sleeve [1] is manufactured of injection moulded plastics material that is adequately flexible and preferably elastomeric. The sleeve comprises a tube [2] suitable for containing radiation emitting therapy medium; a flange [3] at an operatively outer end thereof; and an operatively inner end [4]. The inner end may be either closed or open and, in the event that it is closed, it is provided with lateral drainage holes [5]. The flange is provided with attachment holes [6] arranged suitably for receiving any stitches that may be needed in any particular application.

The sleeve has a length selected such that it extends operatively through the cervix [indicated by numeral [7] in Figure 5] of a patient to terminate in the uterus [indicated by numeral [8] in Figure 5] and the length is, as indicated
above, typically from about 50 mm to about 70 mm. In practice, it would be envisaged that a range of different sizes and lengths would be made available to medical practitioners.

As provided by this invention, this embodiment of radiation therapy sleeve has, towards its inner end, two diametrically opposite, radially extending flexible barb formations [10] that are inherently arranged symmetrically about the axis of the sleeve. The barbs have remote free ends [11] spaced from the outer sleeve surface by a distance providing for co-operation thereof with the uterus wall and that serve, in use, to assist in supporting the weight of the sleeve in the uterus and inhibit natural movement of the therapy sleeve out of its operative position.

The dimensions of the barbs are selected so that they are able to flex towards the sleeve to permit introduction and removal of the sleeve by a clinician or surgeon. The barbs are, in this instance, of circular shape in cross-section and typically would have a cross-sectional diameter of about 0.5 mm with their free ends located approximately 15 mm apart.

Also, the ends of the barbs are shaped so that they do not cause any trauma to the wall of the uterus and this could be achieved simply by suitably rounding the ends or giving them a curve.

In the first embodiment of the invention illustrated in Figure 1, a central region of the length of the sleeve has a slightly enlarged outer diameter providing a bulge [12] in a central region thereof that is adapted to further inhibit natural movement of the sleeve from its operative position.

In the second embodiment of the invention illustrated in Figure 2, the bulge is omitted and the barbs [14] have an elongate rectangular shape in cross-section with the longer dimension of the rectangle extending in a generally circumferential direction relative to the axis of the sleeve. Typically the
thickness of such a barb would be about 0.5 mm and the dimension in the circumferential direction would be about 1.5 to 2 mm. Clearly these dimensions will vary according to the properties of the particular plastics material employed.

In the third embodiment of the invention illustrated in Figure 3, there is illustrated four equally angularly spaced radially extending barbs [16] of the same configuration as is illustrated in Figure 2. The embodiment illustrated in Figure 3 also has a bulge [17].

In the fourth embodiment of the invention illustrated in Figure 4, four equally angularly spaced barbs [18] are shown as being angled to extend somewhat at an incline to the radial direction so that they are angled towards the flange end of the sleeve.

Numerous variations may be made to the embodiments of the invention described above without departing from the scope hereof. In particular, the number and spacing of the barbs may be varied widely as well as their dimensions.

It is envisaged that radiation therapy sleeves according to the invention will behave in a superior manner to those presently in use.
CLAIMS:

1. A cervical radiation therapy sleeve [1] comprising a tube [2] suitable for containing radiation emitting therapy medium, a flange [3] at an operatively outer end thereof, and an operatively inner end [4], the sleeve having a length selected such that it extends operatively through the cervix [7] of a patient to terminate in the uterus [8], the radiation therapy sleeve being characterized in that the sleeve has, towards its inner end, at least two generally radially extending flexible barb formations [10, 14, 16, 18] arranged symmetrically about the axis of the sleeve and having remote free ends [11] spaced from the outer sleeve surface by a distance providing for co-operation thereof with the uterus wall to at least partially support the weight of the sleeve in the uterus and inhibit natural movement of the therapy sleeve out of its operative position but to flex towards the sleeve to permit clinical introduction and removal of the sleeve.

2. A cervical radiation therapy sleeve as claimed in claim 1 in which a central region of the length of the sleeve has a slightly enlarged outer diameter providing a bulge [12, 17] in a central region thereof that is adapted to further inhibit natural movement of the sleeve from its operative position.

3. A cervical radiation therapy sleeve as claimed in either one of claims 1 or 2 in which the radiation therapy sleeve is made of an injection moulded plastics material.

4. A cervical radiation therapy sleeve as claimed in claim 3 in which the sleeve is flexible.

5. A cervical radiation therapy sleeve as claimed in claim 4 in which the radiation therapy sleeve is elastomeric.
6. A cervical radiation therapy sleeve as claimed in any one of the preceding claims in which there are two, three, four, five or six barbs arranged symmetrically about the axis of the sleeve.

7. A cervical radiation therapy sleeve as claimed in any one of the preceding claims in which the barbs [10] are of circular shape in cross-section.

8. A cervical radiation therapy sleeve as claimed in any one of claims 1 to 6 in which the barbs [14, 16, 18] are of elongate rectangular shape in cross-section with the longer dimension of the rectangle extending in a generally circumferential direction relative to the axis of the sleeve.

9. A cervical radiation therapy sleeve as claimed in any one of the preceding claims in which the barbs extend somewhat at an incline to the radial direction so that they are angled somewhat towards the flange end of the sleeve.

10. A cervical radiation therapy sleeve as claimed in any one of the preceding claims in which the outer diameter of the sleeve is about 5 to 6 mm; the diameter of the flange is about 15 mm; and the diameter of a circle encircling the outer extremities of the barbs would be up to about the same as the diameter of the flange, and the length of the sleeve is from about 50 mm to about 70 mm.