

RETRIEVABLE PESSARY

The present invention relates to a retrievable pessary for intravaginal or intrarectal use, which may be inserted and retrieved again once the pharmacologically active ingredient contained therein has been substantially released.

Controlled release pessaries are already known and typically comprise a solid polymer body containing a pharmacologically active substance, which is released in a controlled release or sustained release manner so as to provide a controlled dosage of the active substance over a prolonged time period. One such pessary sold for intravaginal use under the trade mark PROPESS contained a prostaglandin. Prostaglandins play an important role in the gravid uterus, at or near term in pregnancy. They induce structural changes in cervical smooth muscle fibres, resulting in softening and changes in shape that produce a ripening of the cervix. A sustained release of the prostaglandin is required over a time period of several hours just prior to birth. However, whilst these pessaries can be inserted relatively simply by the obstetrician, their removal may pose problems since it may be difficult to find and grip the pessary again.

Intravaginal articles, such as tampons, and intrauterine contraceptive devices are already known, which have strings to allow removal of the device. The

strings are usually attached directly to the device itself. Unfortunately, this is not necessarily appropriate for controlled release devices with which the present invention is concerned, since the solid polymer body containing the pharmacologically active ingredient often lacks the necessary physical strength or integrity to provide a satisfactory anchoring point for the removal string.

It is an object of the present invention to mitigate these problems, and to provide a pessary which is more easily and reliably retrievable.

Generally speaking, the present invention involves using a perforate net having sufficient strength to attach retrieval means thereto.

In particular, the present invention provides a retrievable pessary for intravaginal or intrarectal use which comprises;

- a solid body formed of a water-swellaable polymer comprising a pharmacologically active ingredient adapted to be released in a controlled manner from the body;

- perforate net retaining means formed of a biologically acceptable perforate material and enclosing the solid body and being capable of stretching as the solid body swells; and

- elongate retrieval means formed of a biologically acceptable material and one end

thereof extending from the net retaining means to enable the pessary to be withdrawn from the vagina or rectal cavity after use.

The nature of the solid body is not of primary importance but the invention is particularly applicable to bodies having insufficient strength to retain normal retrieval means.

Generally the solid polymer body is non-biodegradable (in contrast to certain biodegradable or erodable controlled release systems known in the art) such that the solid body is not dispersed inside the patient but requires to be removed after release of the pharmacologically active ingredient to the extent desired. Many such non-biodegradable solid polymer bodies are known in the art and those of the present invention comprise water-swellaable polymers capable of absorbing substantial amounts of aqueous liquid to increase their size several fold. For example, controlled release polymers based on cross-linked polyethylene glycol are capable of swelling to produce a gel which maintains its structural integrity and having linear dimensions of 1.2 to 5, particularly 1.5 to 3 times the original unswollen state. Such swellaable polymer gel systems are typically described in patent specifications GB 2047093 and GB 2047094.

The period of time over which the controlled release of pharmacologically active ingredient is to take place will vary according to the nature of the ingredient and the pharmacological effect to be achieved. In the case of prostaglandins, release is usually required over a relatively short time period, for example 1 to 10 hours. However, the retrievable pessary of the present invention has more general utility for the administration of drugs into the body which may be absorbed through the vaginal or rectal wall into the patient's system. In such cases, controlled release may be arranged to occur over days, weeks or even months according to the nature of the active ingredient and the desired pharmacological effect. Release of the active ingredient may be controlled by diffusion through the solid polymer body to its outer surface, or may be controlled by solubility of the active ingredient in the surrounding body fluid, depending on the nature of the active ingredient itself. The rate of release usually depends on a variety of factors, such as the shape, thickness and degree of cross-linking of the solid polymer body, the nature of the active ingredient and the nature of the polymer itself.

The perforate net retaining means encloses the solid body so as to provide a firm anchorage for the elongate retrieval means, despite any lack of inherent strength in the solid body itself. The perforate net retaining means

is preferably in the form of a pouch which encloses the solid body.

The perforate net retaining means is formed of a biologically-acceptable perforate material, such as a net (including knitted, woven and non-woven materials, synthetic nets and expanded porous films).

Since the polymer swells in use, the pouch may conform to the initial size of the polymer body, yet be capable of stretching as the polymer swells. Knitted structures are particularly useful for this. Alternatively, the material from which the pouch is made may itself have the desired stretchability or elasticity.

It is particularly preferred that the pouch be produced in a seamless manner e.g. by circular knitting, so as to minimise seams or other protrusions which might lead to irritation within the patient. The pouch will usually have a slit, or other aperture for insertion of the solid polymer body.

Usually, the total length of the retrievable pessary is 25-35cm. The pouch is generally of length 1 to 15 cm (preferably 5 to 15 cm for a suppository and 4 to 10 cm for a vaginal pessary) and of width 0.5 to 2 cm.

In one embodiment of the invention, the elongate retrieval means are integrally formed with the pouch, for example by knitting a continuous tape including a pouch portion into which the polymer body is inserted.

In a second embodiment, the elongate retrieval means is separate from the pouch (and is typically in the form of a cord of the type used for withdrawal of tampons) which is integrated into the structure of the pouch during formation thereof. Preferably, the retrieval cord has two long ends and a central section passing down either side of the pouch from its open end and around its closed end. A neck piece may also be provided around the open end of the pouch. This prevents ripping and fraying of the net, and helps prevent accidental removal of the pessary.

The elongate retrieval means are formed of a biologically-acceptable material, typically a synthetic or natural polymer such as a polyester optionally including cotton, and which is texturised or non-texturised.

Embodiments of the present invention will now be described by way of example only with reference to the drawings which are to some extent schematic, wherein:

Figure 1 is a side view of a first embodiment in its initial state;

Figure 2 is a view of the pessary in a swollen state;

Figure 3 is a view of a second embodiment having an integrally formed retrieval tape; and

Figure 4 shows a second embodiment in its swollen state.

The embodiments shown in Figures 1 and 2 comprises a pouch 2 having a neck 4 and enclosing a controlled release

swellable polymer body 6, a withdrawal cord having end portions 8, 10 and a central portion 12 is provided for retrieving the pessary.

The lozenge shaped polymer body 6 has a dry (and wet) length substantially 28mm (48mm), width substantially 9mm (15mm) and thickness 0.8 to 1.1mm (1.9mm) and is formed of a cross-linked polyethylene glycol. On swelling in contact with body fluids, it is capable of expansion of approximately 325% (i.e. takes up 325% by weight of water). The polymer allows for diffusion control release of a pharmacologically active ingredient (for example prostaglandin PGE₂) though many other applicable active ingredients will be known to the skilled man and the present invention is not limited to any particular one of these.

The pouch 2 is netted and formed of a texturised Dacron (RTM) or Diolen (RTM) polyester yarn of a single feed knitted construction formed on a Lilliput knitting machine. The pouch is seamless and produced by circular knitting. The knitted construction imparts extensive elasticity to the pouch, which closely conforms to the shape of the polymer body 6 both in the initial and swollen states. The pouch is closed at one end and has an open end 16 through which the polymer body is introduced during assembly. The mouth area is strengthened by means of a neck piece 4 knitted from the same polyester yarn in a denser construction.

The retrieval cord comprises long end portions 8, 10 and a central portion 12 which extends down opposed sides of the pouch and around its closed end. The cord is sewn into the pouch during formation thereof so as to avoid the use of seams or adhesives.

The cord is sewn into the pouch by making the cord one of the two threads fed to a sewing machine. The cord is sewn down one side and around the end of a tube of the netted material (thereby closing the end), and back up the other side. The pouch is trimmed to shape, before being turned inside out so that the cord runs around the inside of the pouch.

Once the polymer body 6 has been introduced into the net pouch 2, the open end 16 may be closed by means of a knot 14 in the retrieval cord. The free ends of the cord may also be knotted (not shown) or one of the strings can be cut short, so as to effectively leave a single retrieval cord.

The pessary is introduced in its non-swollen state into the patient leaving the retrieval cord hanging out. When retrieval is required, this is simply a matter of gentle pulling on the free ends of the retrieval cord so as to withdraw the swollen pessary.

Figures 3 and 4 show a second embodiment wherein the retrieval means is an integrally formed elongate tape 20. The tape is integrally formed on a double bed Rachelle frame from a texturised Dacron (RTM) polyester yarn and

comprises a pouch portion 22 and a closed end portion 24. A longitudinally extending slot 26 is provided for introducing the polymer body 6. Alternatively, the slot could extend transversely or at an angle to the longitudinal direction. Preferably the slot is adjacent the end of the pouch attached to the retrieval cord, but could in principal be anywhere on the pouch provided that the polymer body is effectively retained. The tape, pouch, closed end and slot may be integrally formed on the knitting machine by appropriate programming thereof. The pouch portion 22 is arranged to be stretchable so as to substantially conform to the shape of the polymer body in both its initial and swollen states.

Insertion is carried out as before by a medical practitioner, and the device may be retrieved after use by means of the withdrawal tape.

Equally, the above-described embodiments could be adapted to take a suppository by minor adjustment of dimensions. A typical suppository is cylindrical with a rounded end and has dry (and wet) dimensions length 40mm (60mm), diameter 10mm (16mm); and a swelling of approximately 220%.



CLAIMS

1. A retrievable pessary for intravaginal or intrarectal use which comprises

- a solid body formed of a water-swellaable polymer comprising a pharmacologically active ingredient adapted to be released in a controlled manner from the body;

-perforate net retaining means formed of a biologically acceptable perforate material and enclosing the solid body and being capable of stretching as the solid body swells; and

- elongate retrieval means formed of a biologically acceptable material and one end thereof extending from the net retaining means to enable the pessary to be withdrawn from the vagina or rectal cavity after use.

2. A pessary according to claim 1, wherein the solid body is non-biodegradable and non-erodable such that the body is not dispersed inside the patient in use.

3. A pessary according to any preceding claim, wherein the solid body is a water-swellaable hydrogel.

4. A pessary according to any preceding claim, wherein the pharmacologically active ingredient is capable of being systemically absorbed into the patient.



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6. A pessary according to claim 5, wherein the net retaining means is a hollow tape provided with a slot to insert the solid body, and an elongate extension forming said retrieval means.

7. A pessary according to claim 6, wherein the hollow tape is integrally formed by knitting.

8. A retrievable pessary for intravaginal or intrarectal use substantially according to any embodiment described in conjunction with the drawings.