9 parts of α,ω-divinylether terminated poly(ethylene oxide)-b-poly(dimethylsiloxane) multiblock copolymer (PEO-b-PDMS), 89 parts of silica-filled poly(dimethylsiloxane-co-vinylmethylsiloxane), 10 ppm Pt-catalyst (of the reactant), 0.03 parts inhibitor (ethynyl cyclohexanol), and approximately 2 parts of poly(hydrogenmethylsiloxane-co-dimethylsiloxane) crosslinker are mixed in a two-roll mill. The mixture is extruded to a tube-like form with a wall thickness of 0.15 mm and cured by heat.

Preparation of the intrauterine system

The membrane tube having the length of 3.1 mm is swollen in isopropanol and pulled over the core. Isopropanol~~Cyclohexane~~ is allowed to evaporate. Thereafter the reservoir is swollen in isopropanol and pulled over the elongated extension of the frame comprising thermoplastic polyurethane composition.~~.~~ Isopropanol~~Cyclohexane~~ is again allowed to evaporate.

Example 4

Core preparation

48.5 parts of PEO-b-PDMS, 49 parts of poly(dimethylsiloxane-covinylmethylsiloxane), 10 ppm Pt-catalyst (of the reactant), 0.02 parts inhibitor (ethynyl cyclohexanol), and approximately 2.4 parts of poly(hydrogenmethylsiloxane-co-dimethylsiloxane) crosslinker are mixed in a two-roll mill. The mixture is extruded to form a rod with an outer diameter of 2.1 mm and cured by heat at + 150 °C for 15 minutes, during which crosslinking takes place. The crosslinked core is cut into the length of 15 mm.

The second core is prepared according to Example 3. The crosslinked core having an outer diameter of 2.1 mm is cut into the length of 10 mm.

Preparation of the membrane and the reservoir

9 parts of PEO-b-PDMS, 89 parts of silica-filled poly(dimethylsiloxane-co-vinylmethyl-siloxane), 10 ppm Pt-catalyst (of the reactant), 0.03 parts inhibitor

Claims

1. An intrauterine~~intra-uterine~~ system for a long-term insertion into a uterine cavity, characterized in that said intrauterine~~intra-uterine~~ system comprises a reservoir and a frame, wherein said frame is a continuous, closed and flexible frame of triangular or pentagonal~~polygonal~~ shape which is tapered towards the cervix, and wherein said reservoir is a rod-like elongated element having at least one end ~~of the reservoir is~~ connected to the inner surface of the frame and said~~the~~ reservoir comprises at least one core containing at least one therapeutically active substance and a polymer layer encasing the core.

~~2. An intrauterine system according to claim 1, characterized in that the frame is triangular or pentagonal.~~

23. An intrauterine~~intra-uterine~~ system according to claim 1 ~~or 2~~, characterized in that the frame and the reservoir comprise a flexible polymer composition.

34. An intrauterine~~intra-uterine~~ system according to claim 23, characterized in that the polymer composition comprises siloxane based elastomer, thermoplastic polyurethane, thermoplastic polyurethane elastomer, EVA, polyethylene, thermoplastic polyurethane silicone elastomer or a mixture of at least two of them.

45. An intrauterine~~intra-uterine~~ system according to claim 34, characterized in that the polymer composition of the frame and the reservoir is the same or different.

56. An intrauterine~~intra-uterine~~ system according to any one of claims 1-45, characterized in that the cross section of the frame is circular, semi-circular, oval, flat, elliptical, rectangular, angular, polygonal or star-shaped.

67. An intrauterine~~intra-uterine~~ system according to any of claims 1-56, characterized in that the cross section of the reservoir is circular, oval, flat, elliptical, rectangular, angular, polygonal or star-shaped.

~~8. An intra-uterine system according to any of claims 1-7, characterized in that the reservoir comprises at least one core.~~

~~9. An intra-uterine system according to any of claims 1-8, characterized in that at least one of the cores of the reservoir is encased by a polymer layer.~~

7~~10~~. An intrauterine~~intra-uterine~~ system according to claim 1~~9~~, characterized in that the polymer composition of said at least one core and the polymer layer encasing the core are the same or different.

8~~11~~. An intrauterine~~intra-uterine~~ system according to any of claims 1-7~~10~~, characterized in that the frame comprises a supporting means consisting of a polymer composition or a biocompatible metal.

9~~12~~. An intrauterine system according to any of claims 1-8~~11~~, characterized in that it comprises threads for removal, location or detection of the system.

10~~13~~. An intrauterine system according to any of claims 1-9~~12~~, characterized in that said system comprises at least one image enhancing means for improving the detection and/or location of the ~~of the~~ system.

11~~14~~. An intrauterine system according to claim 10~~13~~, characterized in that the image enhancing means are selected from the group consisting of

a) an inert metal coating on at least part of the body of the intrauterine system;

b) inert metal inserts, clips, rings or sleeves fixedly positioned on the body of the intrauterine system;

c) metal or ferromagnetic powder or particles or suitable metal or alkali metal salts mixed during the compounding step in the raw materials of the frame, core or membrane of the intrauterine system, and

d) a metallic cup, connector, adapter, clamp, sleeve or holder fixed at a suitable position on the frame, which can also be used to anchor or join the reservoir onto the frame.

1215. An intrauterine system according to any of claims 1-1114, characterized in that the frame or the reservoir comprises retention or locking means to retain the reservoir and to prevent it from sliding off.

1316. A method for manufacturing an intrauterine system having a frame and a reservoir, wherein said frame is a closed continuous and flexible frame of triangular or pentagonalpolygonal shape which is tapered towards the cervix, and saida reservoir is a rod-like elongated element having at least one endcomprising at least one therapeutically active substance, which reservoir is connected to the inner surface of the frame, said reservoir comprising at least one core containing at least one therapeutically active substance and a membrane encasing the core,

said method comprising injection molding, extruding or compressing the frame and the reservoir simultaneously, or by using a sequential process comprising the steps of preparing the frame, preparing the first composition comprising a therapeutically active substance and a polymer composition to provide a core, preparing the second composition comprising a polymer composition to provide a membrane encasing the core, combining the core and the membrane to produce a reservoir, and connecting together the reservoir and the frame.

~~17. A method for delivering a therapeutically active substance to a female mammal, said method comprising the steps of preparing an intrauterine system comprising a continuous, closed and flexible frame of polygonal shape and a reservoir connected to the inner surface of the frame, wherein the reservoir comprises at least one core comprising a polymer composition and a therapeutically active substance mixed therein, positioning and maintaining the intrauterine system in the uterus of the female mammal for a period of time sufficient to deliver an effective amount of the therapeutically active substance to the female mammal.~~