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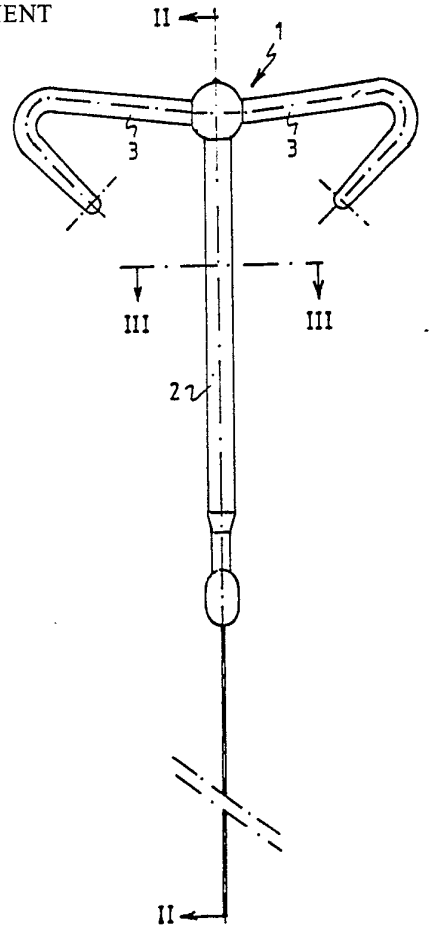
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(54) Title: PROCESS FOR THE MANUFACTURE OF A CARRIER OR IUD PROVIDED WITH A PULLING ELEMENT, AND A CARRIER OR IUD PROVIDED WITH A PULLING ELEMENT

(57) Abstract

Process for the manufacture of a intra-uterine device or IUD, provided with a pulling element. The IUD is an essentially T-shaped plastic element (1) with a middle leg (2). The thread is laid in the injection mould in the lengthwise direction of the middle leg (2) of the IUD. Then the mould is closed and the IUD is subsequently produced by injection moulding, following which the IUD is removed from the mould. The IUD is characterized in that the thread runs along the entire length of the IUD and the IUD is molded of resiliently flexible plastic material such as polyethylene and the thread is a single smooth thread made of another plastic material with a higher fusion temperature such as nylon, polypropylene. Preferably the IUD is a contraceptive of the coil type which is an essentially T-shaped plastic element (1), which T-shaped element has a middle leg (2) on which a so-called coil is wound, while cross pieces of the T-shape serve to hold the IUD in place with a thread fastened at the free end of the middle leg (2). This thread is single and the IUD is cast around it, for example by injection moulding.



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Process for the manufacture of a carrier or IUD provided with a pulling element, and a carrier or IUD provided with a pulling element.

The invention relates to a process for the manufacture of a intra-uterine device or IUD provided with a pulling element, and a device which is used for placing in the uterus or uterine cavity, generally known by the name of IUD (intrauterine device), which device comprises a stem or middle leg and two arms directed sideways, while a pulling element is fixed near the free end of the middle leg.

Such IUDs are generally known and are used for insertion into the uterine cavity of a woman, in which case, for example, a contraceptive such as a copper coil or a product which has to be absorbed slowly in the body is fitted around or placed on the middle leg or the laterally directed projections of the IUD.

Such a device has been described in the US patent number 3,407,806 and which relates to an IUD, with a body which comprises a base portion with a pair of arcuate flanks and an intergral cylindrical connector. A strand is connected to the base portion, preferably by being embedded during molding within the connector. However, the strand has been molded for such a short distance in the IUD, that both ends of the strand need to be used and to tie the strand properly to the IUD it ought to be knotted.

In the US patent number 3,842,826 a device is described which is an intra-uterine contraceptive device (IUD) and to which device is secured a flexible string with a relatively rigid molded line as stiffener and molded in place in the extruded stem portion. The free end of the string carries a small hard ball, molded thereon.

The cross pieces serve to hold the IUD in place in the uterine cavity after the IUD has been inserted into the uterus of a user, while a pulling element must be fitted near the free end of the middle leg for the purpose of permitting easy removal of the IUD subsequently from the uterine cavity. IUDs must be removed from the uterine cavity after a short or longer period of time has elapsed following their insertion into the uterine cavity, for example when the inserted IUD is presumed to be no longer working in the optimum manner, or when complications such as undesirable infections occur. The removal of the IUD can take place by pulling the pulling element projecting out of the cervix or at least lying in the cervix, since the IUD itself generally lies too far up in the uterine cavity for it to be easily gripped with an instrument.

Providing an IUD with a pulling element made of a double thread fixed by means of a knot to the IUD is generally known. For this, the IUD can be provided with, for example, a hole or a narrowed part around which the pulling thread is fastened. It has, however, been found that these pulling threads, which project through the passage of the neck of the womb into the vagina, are responsible for the occurrence of infections in the cervix or in the uterus. It has been found that a thread, and in particular a thread in which there is a knot, is a breeding ground for the accumulation of bacteria, through the fact that these threads have a good adhesion surface for bacteria and the hollows between the threads in the knot are a well-protected place for the accumulation of bacteria. This can, of course, give rise to unpleasant consequences for the user.

The invention provides an improvement of the process for the manufacture of the IUD through the fact that it is characterized in that a thread is first placed in the injection mould for the manufacture of the IUD, this thread being laid fully or partially in the mould in the lengthwise

direction of the middle leg of the IUD, and in that the mould is then closed and the IUD is subsequently produced by injection moulding, following which the IUD is removed from the mould.

With this process according to the invention, a carrier or IUD is obtained with a pulling element which is connected very firmly to the IUD, as a result of which no breakage will occur when it has to be removed again from the uterus, and it is also possible in this way to fasten a single thread to the IUD, which means that possible sources of infection are greatly reduced.

It is preferable, after the IUD is manufactured by injection moulding, to deform the end of the thread near the top side of the IUD. A better fastening of the thread to the IUD is obtained in this way. This can be carried out by, for example, cutting off the end of the thread near the top side of the IUD after the IUD is manufactured by means of injection moulding.

In order to obtain a better connection of the thread to the IUD, the IUD with pulling thread can also be heated up again to such a temperature that the two materials from which the thread and the IUD are made fuse together and the loose end of the thread can also be heated in such a way that the end melts.

The invention also relates to a carrier or IUD of the type described in Claims 7 - 11.

Since the thread according to the invention can now be single, and in particular can be made of a smooth plastic thread, the adhesion surface provides fewer possibilities for bacteria to adhere to it; the total adhesion surface for bacteria is also smaller, since a single thread is used and the chance of infection is thereby reduced accordingly,

while the knot of the type always used hitherto in the thread to fasten this thread to an IUD is no longer present here, which hitherto was the greatest source of undesirable infection.

The invention will be explained in greater detail below with reference to a drawing, in which:

Figure 1 shows an IUD with a pulling element according to the invention;
Figure 2 shows in longitudinal section the IUD along line II-II from Figure 1;
Figure 3 shows in cross-section the IUD along line III-III from Figure 1.
Figure 4 shows a thread with several IUDs.
Figures 5, 6, 7 and 8 show in longitudinal section the IUD along line II-II from figure 1 according to another possibility of putting the thread inside the IUD.

Figure 1 shows an IUD with pulling element according to the invention, which shows a simplified representation of an example of an embodiment of the IUD according to the invention.

The IUD illustrated in Figure 1 comprises a T-shaped carrier element 1 with a middle leg 2 and two cross legs 3. A coil or a product which is to be absorbed slowly by the body is placed on this middle leg 2. These cross legs 3 can also be designed in many other possible ways.

A thread 4 of, for example, polypropylene is fitted in the middle leg 2. This plastic thread 4 runs along the entire length through the middle leg 2. Since this thread 4 runs along the entire length, it is wedged in by the plastic of the middle leg 2 of the IUD cast around it.

Figure 2 shows in longitudinal section, along the line II-II of Figure 1, the middle leg of the IUD. The pulling thread of plastic is preferably cut off near the end 5, at the point where it projects at the top side of the IUD. In another embodiment of the IUD according to the invention the thread is deformed near the top side, for example by temporarily heating it above the melting point of the plastic. Near the loose end 6, the thread is heated above the elastic limit, so that it does not have any sharp edges.

Figure 3 shows, finally, the IUD with pulling thread in cross-section along the line III-III from Figure 1.

Figure 4 shows a thread 4 with several IUDs 1.

A very simple fastening of a pulling thread is obtained in this way. Due to the fact that this thread is single and is made of a smooth plastic, the chance of infections of the cervix and/or the uterus occurring is very greatly reduced compared with the hitherto known IUD with a pulling element. First, the surface of the pulling thread is reduced at least by half, because this thread is single. Secondly, the use of a plastic thread means a reduction of infections, because a thread with smoother surface offers fewer possibilities for bacteria adhering to its surface. Thirdly, the result of leaving out a fastening of a knot or another fastening possibility in which small hollows are produced is a great reduction of the possibility of the accumulation of bacteria.

Figures 5, 6, 7 and 8 show other possibilities of incorporating a plastic thread inside the middle leg of the IUD. Figure 5 shows an IUD with a thread which has a thickness 7 which is incorporated in the top of the IUD. Figure 6 shows a cross-section of the IUD with a thread with several thicknesses, like knobs 7, 8, 9. Figure 7 shows in longitudinal section, along the line II-II figure 1, the middle

leg of the IUD with a thread which is incorporated in the leg in a zigzag way 10. Figure 8 shows, finally, a possibility in which the incorporated thread is coiled inside the leg of the IUD. This thread can be coiled more than once 11.

Claims

1. Process for the manufacture of a intra-uterine device or IUD, provided with a pulling element, that first a thread is placed in the injection mould for the manufacture of the IUD, characterized in that, the IUD is an essentially T-shaped plastic element, with a middle leg and that the thread is laid in the mould in the lengthwise direction of the middle leg of the IUD, and in that then the mould is closed and the IUD is subsequently produced by injection moulding, following which the IUD is removed from the mould.

2. Process according to Claim 1, characterized in that, on the same thread more than one IUD is produced by injection moulding at an intermediate distance of each other.

3. Process according to Claim 1 or 2 characterized in that, after the IUD is produced by injection moulding, the end of the thread near the top side of the IUD is cut off.

4. Process according to Claim 1, 2 or 3 characterized in that, after the IUD is produced by injection moulding, the end of the thread near the top side of the IUD is deformed.

5. IUD manufactured according to any of the processes of Claims 1 to 5, characterized in that the thread runs along the entire length of the IUD and the IUD is molded of resiliently flexible plastic material such as polyethylene and the thread is made of another plastic material with a higher fusion temperature such as nylon, polypropylene.

6. Device for, for example, a contraceptive of the

coil type known by the name of IUD, which carrier comprises, for example, an essentially T-shaped plastic element, which T-shaped element has a middle leg on which a so-called coil is wound, while cross pieces of the T-shape serve to hold the IUD in place after the IUD has been introduced into the uterus of a user, and a thread is fastened at the free end of the middle leg, which thread when the device is in use is situated at least partially in the cervix or neck of the womb, and serves to permit easy removal of the IUD from the uterus, characterized in that this thread is single, and the IUD is cast around it, for example by injection moulding.

7. Carrier according to Claim 6, characterized in that the thread is a single smooth thread made of a plastic, for example nylon, polypropyleen or polyurethaan.

8. Carrier according to Claim 6, characterized in that the thread is situated along the full length of the middle leg or middle piece.

9. Carrier according to Claim 6, characterized in that the thread is at least partially fused with the stem.

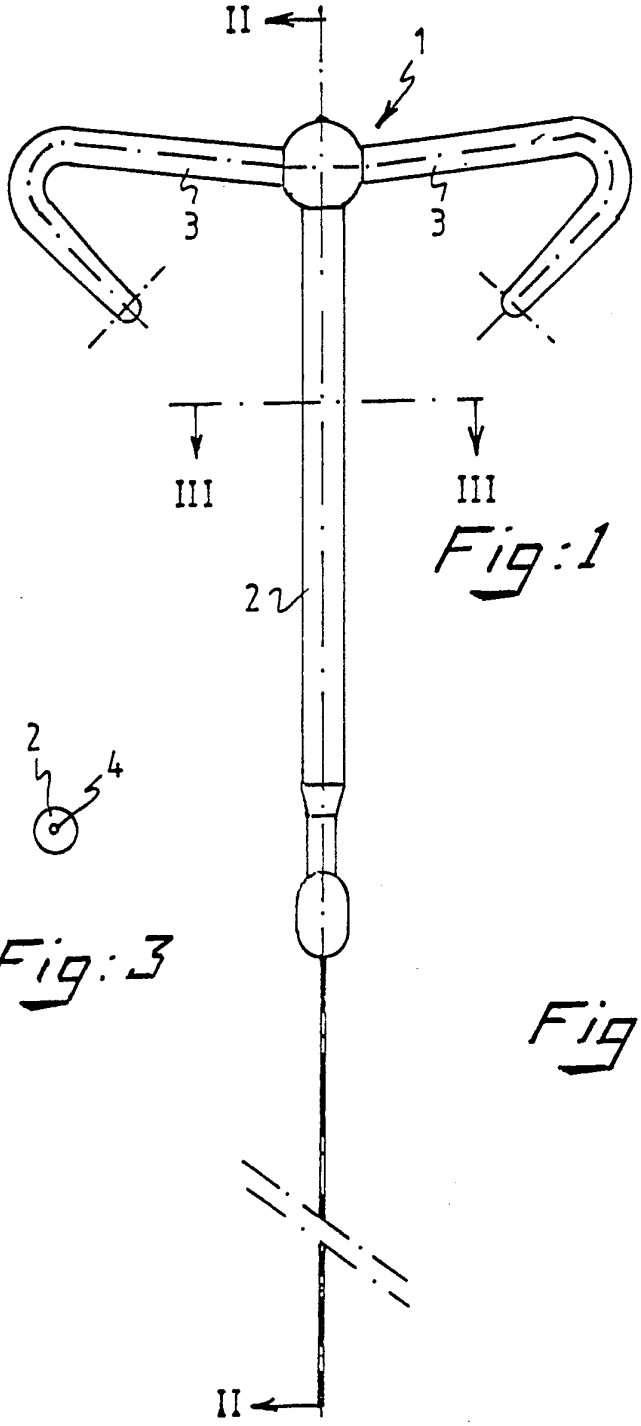


Fig:1

Fig:3

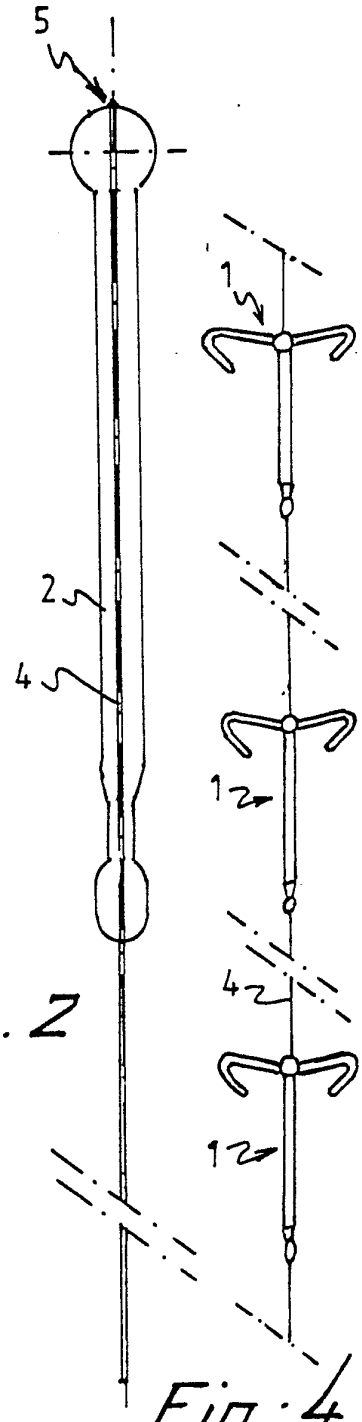


Fig. 2

Fig:4

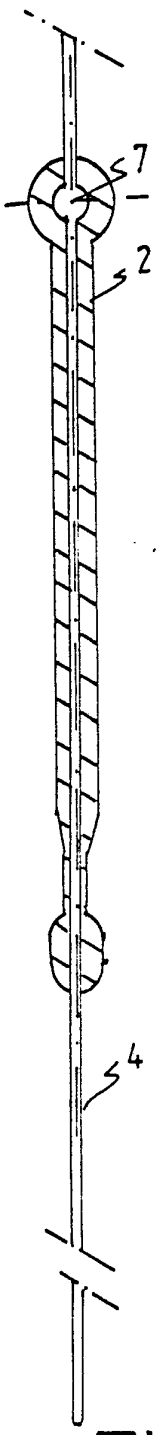


Fig: 5

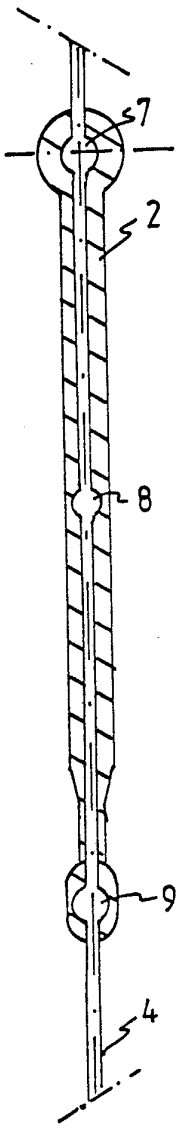


Fig: 6

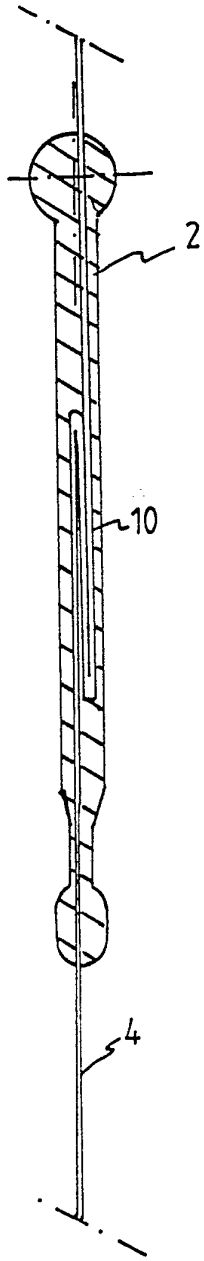


Fig: 7

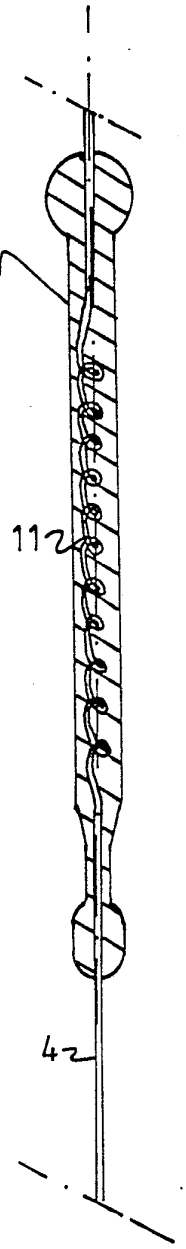


Fig: 8

INTERNATIONAL SEARCH REPORT

International Application No PCT/EP 90/02014

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC[5]: A 61 F 6/14

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
IPC[5]	A 61 F

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
X	US, A, 3407806 (HULKA) 29 October 1968 see claim 1; figures; column 2, lines 41-43 (cited in the application)	1,5,6
Y	--	4,7,8
Y	FR, A, 2431286 (AZOULAY) 15 February 1980 see figures; page 3, lines 27-30	4
	--	
Y	US, A, 3842826 (NOLAN) 22 October 1974 see abstract; figures; column 2, lines 52-63 (cited in the application)	8
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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
21st March 1991	10. 05. 91
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Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages	Relevant to Claim No.
Y	GB, A, 981389 (BIERER) 27 January 1965 see page 1, lines 85-86; figures --	7
A	US, A, 4094313 (KOMAMURA) 13 June 1978 see figures; column 3, lines 15-24	5,10

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. EP 9002014 SA 41972

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 10/04/91
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A- 3407806		None	
FR-A- 2431286	15-02-80	None	
US-A- 3842826	22-10-74	None	
GB-A- 981389		None	
US-A- 4094313	13-06-78	None	