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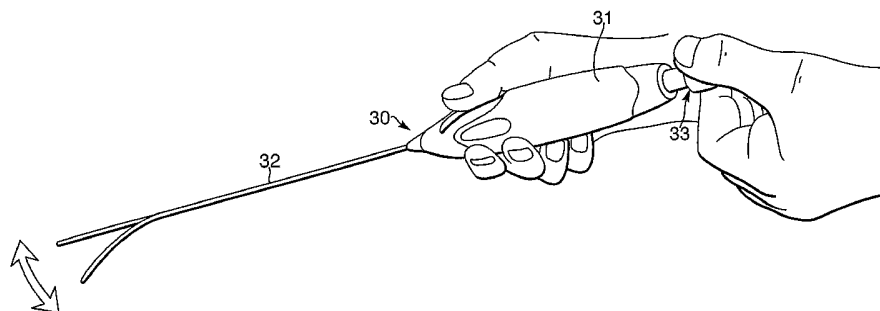
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(54) Title: EMBRYO TRANSFER CATHETERS AND ASSEMBLIES



(57) Abstract: An embryo transfer catheter assembly has a catheter (1), which can be advanced along an outer sheath (2). The catheter (1) has a first passage (13) opening at its tip (15) by which an embryo can be transferred to the uterus. A pull rod (19) attached at one end with the tip (15) of the catheter extends along a second passage (14) alongside the first (13). The other end of the pull rod (19) is attached to a hub (21), which is screw threaded onto the catheter hub (18). The tip (15) of the catheter (1) can be bent to one side by unscrewing the hub (21) of the pull rod (19) from the catheter hub (18) so that it moves rearwardly and pulls the pull rod and the tip of the catheter, thereby bending it to one side. Alternatively, one side of the catheter (30) could include an electrically contractive material (37) so that, when a current is applied, the side reduces in length and pulls the tip to one side.

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EMBRYO TRANSFER CATHETERS AND ASSEMBLIES

This invention relates to assemblies of the kind including an outer sheath and an embryo transfer catheter slidably received within the sheath to project therefrom at its patient end, the catheter having a first passage therein for containing an embryo and an opening towards its patient end through which the embryo can be expelled.

Embryo transfer catheters are used to transfer an embryo to the uterus of a patient. The catheter is usually introduced through the cervix by sliding along a shorter outer sheath, which provides greater rigidity and thereby facilitates introduction. The catheter itself is preferably flexible with a soft, rounded tip to reduce the risk of damage to the lining of the uterus. This procedure is described in greater detail in GB 2209673.

It is an object of the present invention to provide an alternative embryo transfer catheter and assembly.

According to one aspect of the present invention there is provided an assembly of the above-specified kind, characterised in that the assembly is arranged to enable the tip of the catheter to be bent by the user while it is position in the patient.

The catheter may include an elongate member extending along and attached with the catheter towards its patient end and accessible towards the machine end of the catheter whereby the patient end of the catheter protruding from the sheath can be steered by manipulating the machine end of the elongate member. The elongate member is preferably a pull rod that can be pulled to cause the patient end of the catheter to bend. The elongate member may be attached to a rotatable member at the machine end that is rotated to displace the elongate member axially and bend the patient end of the catheter. The catheter preferably has a second passage along which the elongate member extends. Alternatively, the catheter may include an electrical arrangement for bending the tip of the catheter. The electrical arrangement may include a material that changes length when a current flows through it, the material extending along a part at least of the length of the catheter. The assembly may

include a handle containing a battery and a switch arranged to control the supply of power to the electrical arrangement.

According to another aspect of the present invention there is provided a catheter for an assembly according to the above one aspect of the present invention.

Embryo transfer catheter assemblies according to the present invention, will now be described, by way of example, with reference to the accompanying drawings, in which:

- Figure 1 is a perspective view of the assembly;
- Figure 2 is a perspective view of the patient end of the assembly showing the tip of the catheter bent;
- Figure 3 is a partly cut-away view of the patient end of the catheter;
- Figure 4 is a cross-sectional side elevation view of the machine end of the catheter;
- Figure 5 is a perspective view of an alternative catheter;
- Figure 6 is an enlarged perspective view of a part of the catheter in Figure 5; and
- Figure 7 is a cut-away view through the shaft of the catheter of Figures 5 and 6.

With reference first to Figures 1 to 4, the assembly comprises an embryo transfer catheter 1 and an outer sheath 2 within which the catheter is slidable.

The catheter 1 has a shaft 10 and a hub assembly 11 at its machine end 12. The shaft 10 is either 180mm or 230mm long and is extruded from a flexible plastics material such as

PVC or polyurethane with a figure-of-eight cross-section having two circular bores 13 and 14 extending side-by-side along its length. One bore 13 is for use in receiving and transferring an embryo and opens at the patient end 15 of the shaft 10 through a side aperture 16. The patient end 15 of the shaft 10 is smoothly rounded and atraumatic. The other end of the bore 13 opens through a side port 17 extending radially outwardly at an angle from a forward hub body 18. The other bore 14 has a slightly larger diameter and provides a channel for a flexible pull rod 19 or similar elongate member. The pull rod 19 may be of various different materials such as metal, plastics, glass fibre or the like, providing it can slide freely along the bore 14 and is relatively inextensible. The forward end of the rod 19 is attached fixedly with the patient end 15 of the shaft 10 and the rear end passes through a bore 20 in the forward hub body 18, being attached fixedly with a rear hub body 21. Both the forward and rear hub bodies 18 and 21 have knurls 22 to assist gripping

The forward hub body 18 has an externally-threaded boss 23 through which the bore 20 and pull rod 19 extend, the boss extending axially rearwardly of the hub body. The rear hub body 21 has an internally-threaded sleeve 24 extending axially forwardly and screwed onto the boss 23 of the forward body 18. If the rear hub body 21 is twisted anticlockwise relative to the forward body 18, it is jacked rearwardly relative to the forward body, thereby pulling back the pull rod 19. Because the pull rod bore 14 extends on one side of the shaft 10, pulling on the rod 19 will bend the patient end 15 of the shaft to one side, in the direction of the pull rod bore, as seen in Figure 2. If, instead, the rear hub body 21 is screwed in a clockwise direction, it moves towards the forward body 18, thereby allowing the pull rod 19 to move forwardly and the shaft 10 to straighten.

In use, the assembly of the catheter 1 and sheath 2 is inserted through the cervix with the catheter initially pulled back so that its tip 15 is level with the forward end of the sheath. The assembly has sufficient stiffness to be pushed through the cervix without buckling. When the sheath 2 has been inserted to the desired depth, the catheter 1 can be pushed forwardly so that it slides relative to the sheath. The catheter 1 is then manipulated to bring its opening 16 to the desired location. Where necessary, the tip 15 of the catheter 1 can be bent by adjustment of the relative axial spacing of the forward and rear hub bodies 18 and 21. When

correctly located, the embryo is ejected through the opening 16 by fluid pressure, such as that exerted by means of a syringe connected to the port 17.

The invention could be modified in various ways. For example, instead of a pull rod, the catheter could have a relatively stiff elongate member so that it could be pushed to deflect the end of the shaft in the opposite direction. There are many arrangements by which the pull rod or other elongate member could be displaced instead of the threaded arrangement described above. For example, the elongate member could simply have a handle that was pulled or pushed, or there could be some form of cam or lever operable to move the elongate member forwardly or rearwardly.

The shaft of the catheter could be bent in other ways than by means of an elongate rod that is pulled or pushed. Instead, for example, the catheter shaft could be bent electrically, as shown in Figures 5 to 7. The catheter 30 shown in Figures 5 to 7 has a handle 31 and a shaft 32. The handle 31 has torpedo shape and contains an integral syringe with a plunger 33, which projects from the rear of the handle. The plunger 33 has a twist lock so that it can be locked in its outer position, as shown in Figures 5 and 6, and has to be twisted to unlock it before the clinician can push it in to eject the embryo from the catheter. The handle 31 also houses a battery and electronics (not shown) and has two push buttons 34 and 35 towards its forward, patient end, which the clinician presses to bend or straighten respectively the tip of the catheter.

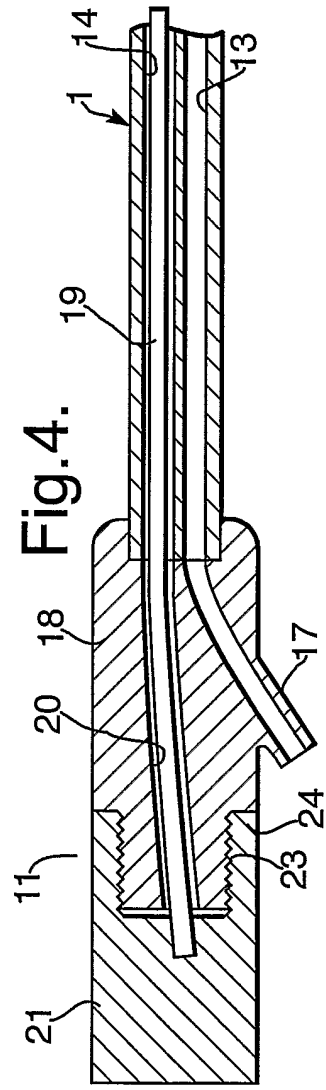
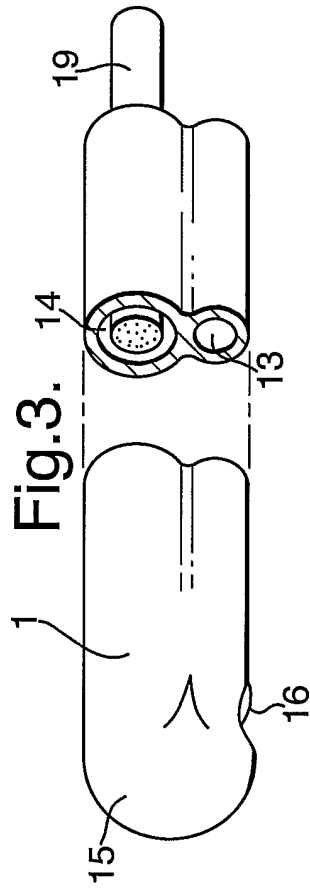
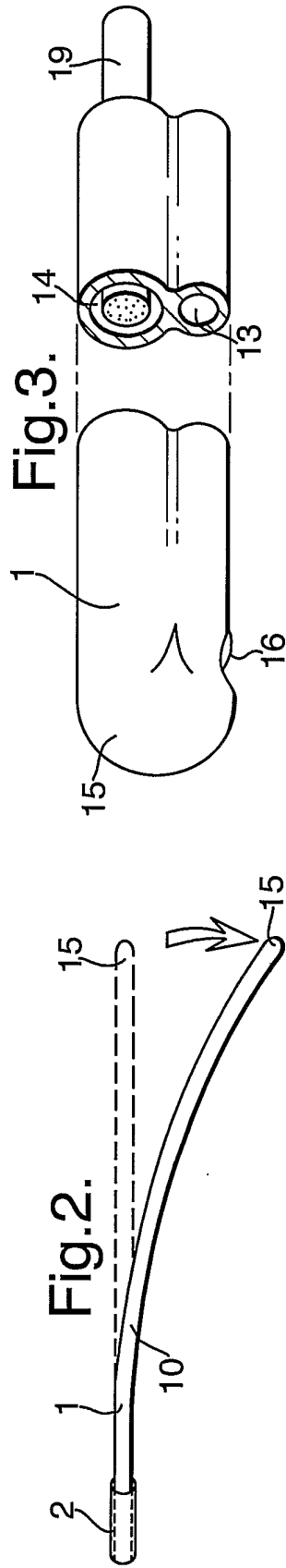
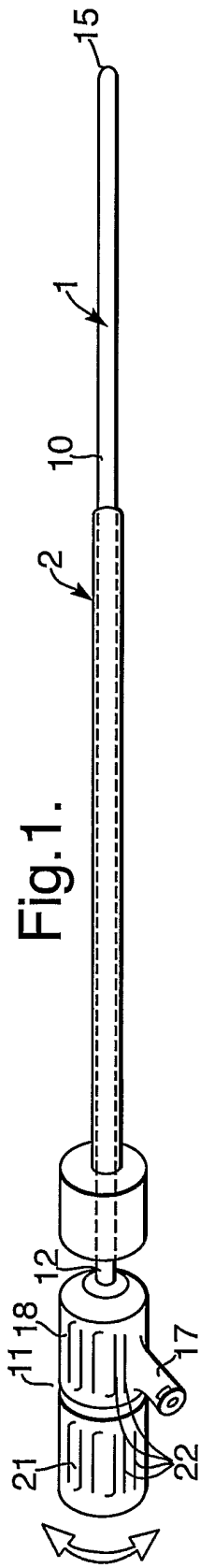
The shaft 32 of the catheter is shown most clearly in Figure 7. The shaft 32 has a central bore 36 and is divided into two parts 37 and 38 across its diameter. One part 37 is of a material that contracts when an electrical current is applied to it, such as including an electrostrictive material. The other part 38 is of an electrically insulating plastics material and has an electrical wire 39 extending along its length. At its patient end, the wire 39 connects with the patient end of the contractive part 37. The machine end of the contractive part 37 connects with the electronics in the handle 31. When the clinician presses the "Bend" button 34, the electronics within the handle 31 applies a current to the wire 39 so that current flows through the contractive part 37. This causes the contractive part 37 to reduce in length, thereby bending the shaft 32 with the contractive part on the inside of the bend. The clinician

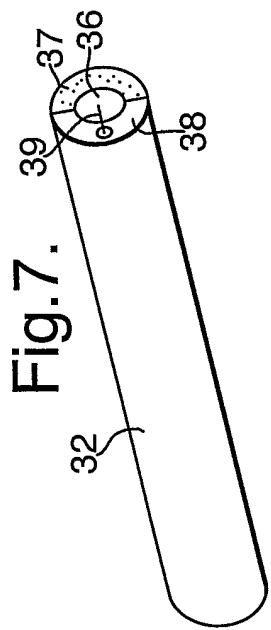
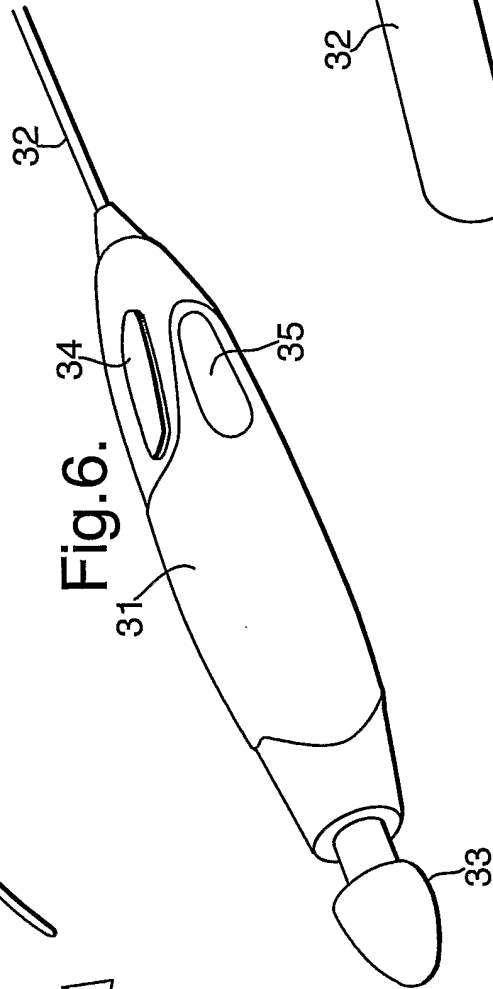
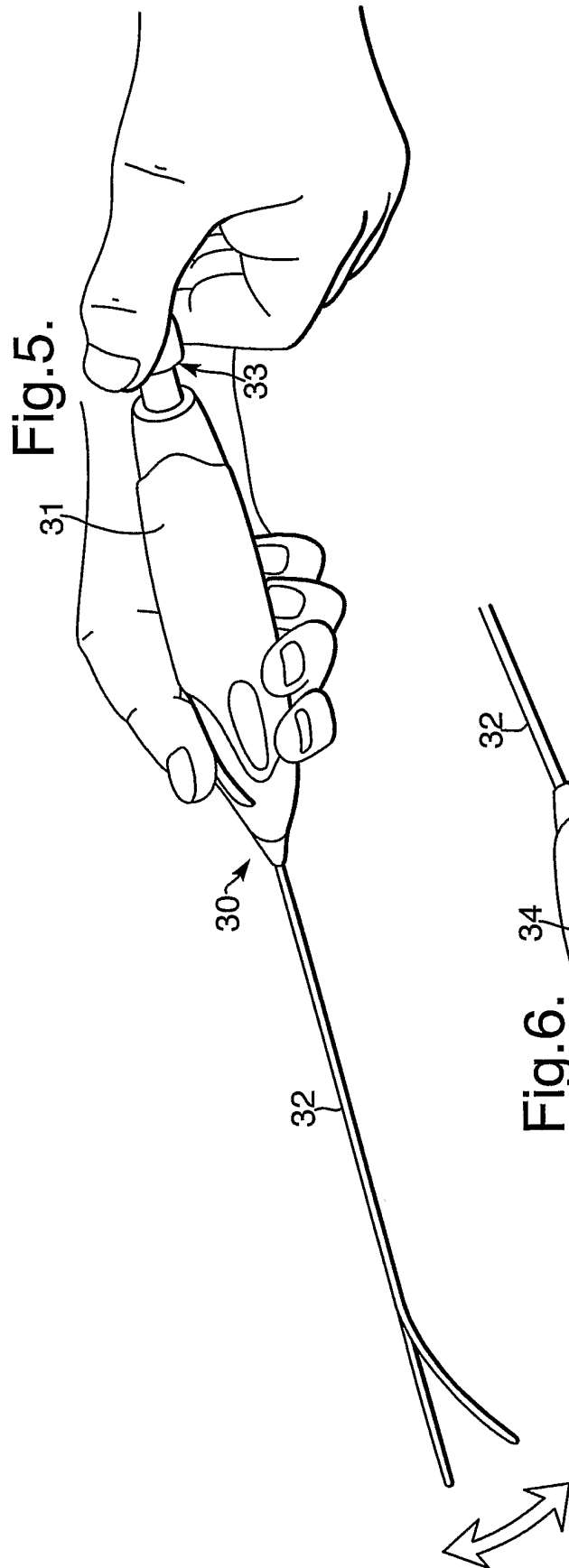
can then release the plunger 32 and eject the embryo. When this has been done he presses the "Straighten" button 35 causing termination of current to the contractive part 37. The contractive material need not extend along the entire length of the shaft 32 since it may only be necessary for a few centimetres at the tip of the catheter to bend. It will be appreciated that, instead of a material that contracts, it would be possible to provide a shaft with a material that expands when current is applied to it. Such a shaft would bend with the expansible part on the outside of the bend.

CLAIMS

1. An assembly of an outer sheath (2) and an embryo transfer catheter (1) slidably received within the sheath to project therefrom at its patient end, the catheter having a first passage (13) therein for containing an embryo and an opening (16) towards its patient end (15) through which the embryo can be expelled, characterised in that the assembly is arranged to enable the tip (15) of the catheter (1) to be bent by the user while it is position in the patient.
2. An assembly according to Claim 1, characterised in that the catheter (1) includes an elongate member (19) extending along and attached with the catheter towards its patient end (15) and accessible towards the machine end (12) of the catheter whereby the patient end of the catheter protruding from the sheath (2) can be steered by manipulating the machine end (21) of the elongate member.
3. An assembly according to Claim 2, characterised in that the elongate member is a pull rod (19) that can be pulled to cause the patient end (15) of the catheter (1) to bend.
4. An assembly according to Claim 2 or 3, characterised in that the elongate member (19) is attached to a rotatable member (21) at the machine end that is rotated to displace the elongate member axially and bend the patient end (15) of the catheter (1).
5. An assembly according to any one of Claims 2 to 4, characterised in that the catheter (1) has a second passage (14) along which the elongate member (19) extends.
6. An assembly according to Claim 1, characterised in that the catheter includes an electrical arrangement (31, 34, 35, 37, 39) for bending the tip of the catheter.
7. An assembly according to Claim 6, characterised in that the electrical arrangement includes a material (37) that changes length when a current flows through it, and that the material (37) extends along a part at least of the length of the catheter.

8. An assembly according to Claim 6 or 7, characterised in that the assembly includes a handle (31) containing a battery and a switch (34, 35) arranged to control the supply of power to the electrical arrangement (37, 39).
9. A catheter (1) for an assembly according to any one of the preceding claims.





INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61M25/00 A61B17/435				
According to International Patent Classification (IPC) or to both national classification and IPC				
B. FIELDS SEARCHED				
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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched				
Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal, WPI Data				
C. DOCUMENTS CONSIDERED TO BE RELEVANT				
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.		
X	US 2002/156346 A1 (KAMRAVA MICHAEL M ET AL) 24 October 2002 (2002-10-24)	1-3,5,9		
Y	paragraph '0033!; figures 1,4	6-8		
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Y	column 10, line 41 - line 54	6-8		
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Y	page 1, line 33 - page 2, line 10; figures 1,9,10	6-8		
Y	WO 95/06494 A (INTELLIWIRE INC) 9 March 1995 (1995-03-09)	6-8		
	page 3, line 25 - line 28; figure 7			
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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