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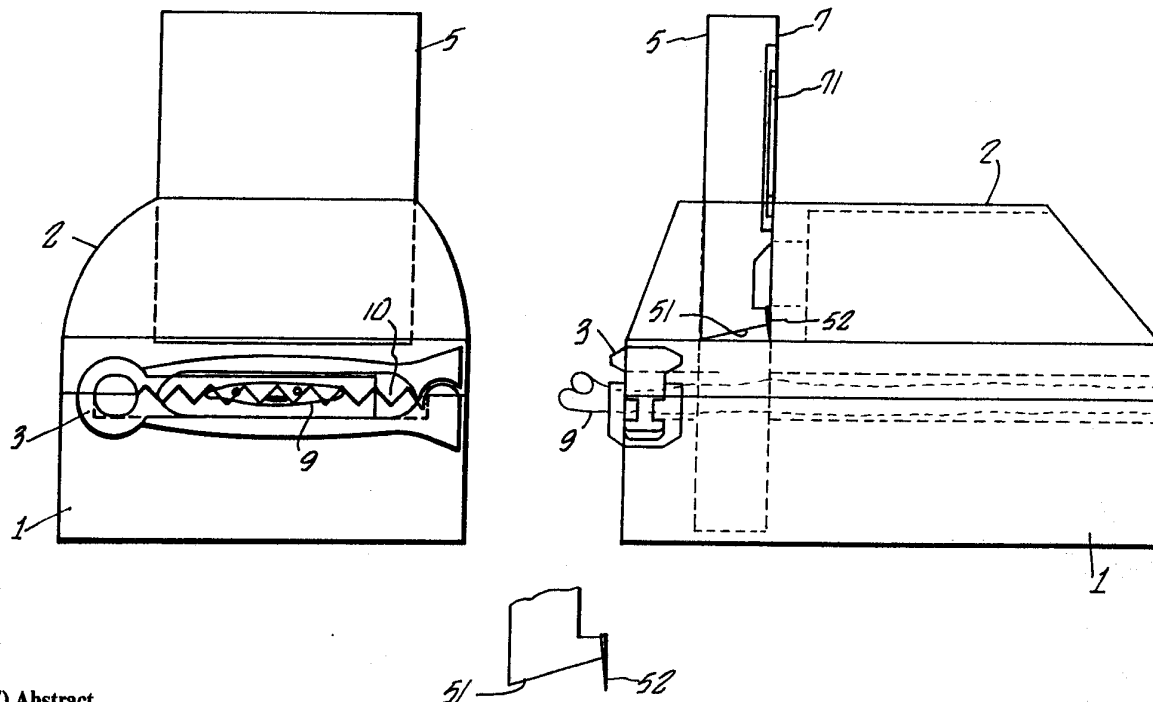
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With amended claims.*

(54) Title: CORD CUTTER SAMPLER



(57) Abstract

There is disclosed herein a device and method for clamping and cutting an umbilical cord so as to enable blood samples to be collected. Clamps (3) are provided as either part of the device or separate therefrom to clamp off a section of the umbilical cord for the cutting and sampling process. The device includes a housing (1, 2) which accommodates vials (4) for receiving the blood samples.

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DESCRIPTION

CORD CUTTER SAMPLER

This invention relates to the field of obstetrics and more particularly to an improved apparatus and method for cutting and collecting blood from an umbilical cord.

BACKGROUND OF THE INVENTION

- 5 The current process in the delivery of babies requires that the umbilical cord is cut shortly after the moment of birth. The function of the cord is the transmission, between mother and baby, of nutrients and oxygen through the blood flowing in the cord. The cord is thus
- 10 engorged with blood at birth when severed by the obstetrician to free the baby from the mother. Samples of the blood in the cord are commonly collected at birth for chemical and biological assay to determine if the newborn is subject to possible genetically transmitted diseases.
- 15 Currently, the procedure calls for the placement of a small clamp close to the newborn to stop the flow of blood in the cord. At the moment of birth there is a great deal of fluid present, including blood and amniotic fluid from the mother, making the physician's gloved hands
- 20 slippery. The combination of the small clamp size and the fluid on the gloves creates difficulty in applying the clamp. A second, typically reusable, metal clamp is then applied a short distance from the small clamp toward the mother creating a segregated pocket for cutting. A
- 25 scissors cut is then made in the center of the pocket by the physician to separate the baby. This formed pocket is under high pressure created by the placement of the two clamps and, upon cutting, the trapped blood within spurts, spraying the general area to as much as ten feet away.
- 30 Because of the possibility of blood carried diseases this spurting endangers medical personnel. After the baby is removed from the area an attempt is made to obtain a specimen of blood from the section of cord attached to the

placenta.

Common practices to obtain this blood include the draining of the cord segment directly into an open vial or direct extraction from the cord by syringe and needle.

5 The draining method requires one person to hold an open ended sample vial below the cord opening while a second person opens the metal clamp and attempts to direct the blood flow into the opening. In most cases the cord segment must be hand "milked" by squeezing the segment

10 toward the vial, probably causing many contaminants to flow into the vial including mother's vaginal blood, amniotic fluids and Wharton's gel which may affect the blood testing. When a syringe and needle is used to extract the blood directly from the cord, care must be

15 taken to prevent inadvertent needle sticks. The contents from the syringe must then be transferred into appropriate vials requiring further manipulation of needles and syringes along with the associated risk. Either blood collection method leaves contamination from blood on the

20 external portions of the vials making it difficult to apply or retrieve patient labels.

SUMMARY OF THE INVENTION

The present invention involves a device and method which provide a much improved method of performing

25 the above described procedure. This device and method accomplish the above procedure in a simple and convenient manner, causing little or no exposure of the medical personnel to inadvertent blood splash, and present clean and adequate samples of cord blood to the physician.

30 According to an exemplary embodiment of the invention, a device comprises a holding mechanism having pre-attached blood collection vials which fits over an umbilical cord, an umbilical clamp which separates from the housing and remains attached to the infant, a hidden

35 moveable blade which severs the cord through secondary action, means for connecting the open cut blood vessels

directly into the blood collection vials, and a secondary clamp to preclude spillage of the cut segment upon removal of the vials. The umbilical clamp and secondary clamp may be separate from the device itself. Because of the simple construction of the device and its use of existing components to collect the blood, it can be manufactured for very low costs and can therefore be disposed after use, precluding the possibility of transmitting diseases to other personnel.

10 Accordingly, it is a principal object of the present invention to provide a new form of device for cutting and sampling blood from an umbilical cord.

Another object of the present invention is to provide a new method for cutting and sampling blood from an umbilical cord.

These and other objects and features of the present invention will become better understood through a consideration of the following description, taken in conjunction with the drawings in which:

20 DESCRIPTION OF THE DRAWINGS

Figure I is a front view of a device constructed in accordance with the present invention in an open position;

Figure Ia is a similar front view with an umbilical cord clamp removed from the device;

Figure II is a front view on the left side and a side view on the right of the device in a closed position;

Figure III is a front view on the left and side view on the right of the device in a cut position;

Figure IV comprises detailed views illustrating the cam action of the present device; and

Figure V comprises detailed views illustrating button action of the device.

DETAILED DESCRIPTION

35 An embodiment of the present invention is shown in the attached drawings. This embodiment comprises two

housings; a bottom housing 1 and a top housing 2 hinged about a common pivot point and having an elongated opening suitable for placement around an exposed umbilical cord. The proximal end of the housing mechanism contains an
5 opened plastic clamp 3 used to permanently clamp the cord near the newborn baby. The most common clamp used today is depicted in the drawing (manufactured by Hollister). Placing the open housing assembly over the cord and closing the unit over the cord will permanently lock the
10 umbilical clamp in place.

A sliding blade 5, is now positioned directly behind the clamp and over the now entrapped section of clamp 3. Movement of the blade 5 in a downward direction will first squeeze the blood in the cord directly next to
15 the clamp 3 back toward the housing by means of the slanted surface 51 before the cutting blade 52 severs the cord thus greatly reducing the blood available for spurting. The cut itself occurs in a closed chamber formed by the housings 1 & 2 and the blade 5, thus protecting the
20 external area from blood during the cutting process.

The inner surfaces of the housings 1 & 2 are coated with suitable amounts of a easily formable gel 20 which makes suitable seals with both the housing surfaces and the cord tissue. Upon the closing of the housings
25 around the cord this gel 20 forms into the interstitial spaces between the housings and the human cord thereby creating an airtight seal. The gel 20 protrudes into the chamber 53 beneath the blade 5 so the severing action creates a flat cross section of cord surrounded by the
30 gel 20 in an air tight formation. Common dentifrice adhesive has worked exceedingly well in this application.

The rear surface of the blade 5 is covered with a soft rubber gasket 7 which has an internal depression 71 shaped to match the inner surfaces of the closed housing.
35 When the blade 5 is positioned in its down location, an elongated slot in the depression mates with the oval

openings in the housing allowing blood from the severed vessels to spill into this depression.

Attached to the top housing 2 are two blood vials 4 held in place by a common yoke 8. These containers comprise a glass test tube 41 capped by a thick rubber plug 42. Two vials are needed since one of the vials will contain an anticoagulant. Both coagulated and non coagulated blood are required for the testing. The vials depicted in the illustration are common to the industry and are typically sold with an internal vacuum within the tube 41 such that upon penetration of a needle the vacuum will pull fluid into the tube automatically.

Placed only partially within the rubber plug 42 are needles 61 directly coupled to needle blocks 6 formed of a solid material with an inclined cam surface 62 and having a through hole 63 in direct communication with the needle bore. The blocks 6 are initially located in cavities 53 built into the blade 5. The cavities have a reverse cam surface 54 making direct contact with the cam surface 62. Downward movement of the blade 5 causes the blocks 6 to be pushed forward causing the needles 61 to penetrate through the plugs 42 into the vials making direct communication with the vacuum in the tubes 41. When the blade 5 is positioned in its down location, a second elongated slot in the depression in the gasket 7 mates with the openings in the blocks 6 making communication directly to the severed vessels through the first slot in the depression.

When the blade 5 severs the cord a pulling movement away from the newborn will release the umbilical clamp 3 from the housing assembly as well as a short cord stub. The portion of the cord attached to the placenta will have the clamped assembly anchored onto its end along with the vials 4. Methods of anchoring could be the gel 20 by itself, hook and loop fasteners like that sold under the trademark Velcro glued to the inner housing

surfaces and/or localized projections within the formed cord area. In any case the removal of the vials 4 from the housing would result in the now exposed and communicated needles 61 dripping blood which is not acceptable.

- 5 To preclude this exposure a button 8 attached to the yoke must be activated in a downward direction to move the yoke away from the vials 4 allowing their release. The bottom surface of the button/yoke 8 will move with this downward motion and clamp the trapped cord between its surface and
10 the inner surface of the bottom housing 1 thus preventing any further bleeding.

It can be seen that this device presents a much improved and safer method of clamping and cutting the umbilical cord than is currently available. The device
15 also presents dual samples of cord blood without additional procedures. Because of the compactness and packaging of the device it can be seen that protective coverings can easily be manufactured to protect even the external surfaces of the vials 4.

- 20 While an embodiment of the present invention has been shown and described, various modifications may be made without departing from the scope of the present invention, and all such modifications and equivalents are intended to be covered.

WHAT IS CLAIMED IS:

1. Apparatus for cutting an umbilical cord and collecting blood samples therefrom comprising
housing means for receiving and entrapping a
5 section of umbilical cord,
cutting means for cutting an entrapped section of the cord, and
said housing means comprising means for holding
vial means for receiving blood from the umbilical cord.
- 10 2. Apparatus as in Claim 1 further including first and second clamp means for clamping ends of the section of umbilical cord.

AMENDED CLAIMS

[received by the International Bureau on 24 August 1992 (24.08.92); original claims 1 and 2 unchanged; new claims 3-13 added; (6 pages)]

1. Apparatus for cutting an umbilical cord and collecting blood samples therefrom comprising housing means for receiving and entrapping a section
5 of umbilical cord,
cutting means for cutting an entrapped section of the cord, and
said housing means comprising means for holding vial means for receiving blood from the umbilical cord.
- 10 2. Apparatus as in Claim 1 further including first and second clamp means for clamping ends of the section of umbilical cord.
3. Apparatus for cutting an umbilical cord and collecting a blood sample therefrom comprising
15 housing means for receiving and entrapping a section of umbilical cord,
cutting means for cutting an entrapped section of the cord and sealing at least one cut end of said cord, and
said housing means comprising means for holding and
20 connecting vial means to provide fluid communication between the vial means and the end of the cord sealed by the cutting means thereby enabling the vial means to receive blood from the umbilical cord.
4. Apparatus as in Claim 3 further including first
25 and second clamp means for clamping ends of the section of umbilical cord.
5. Apparatus as in Claim 3 further including clamp means for clamping at least one end of the section of umbilical cord.
- 30 6. Apparatus for cutting an umbilical cord and

collecting a blood sample therefrom comprising

a housing for receiving and entrapping a section of umbilical cord,

a cutter for cutting an entrapped section of the cord
5 and securely holding and sealing at least one cut end of said cord, and

said housing providing sealed fluid communication between the cut end of the cord and a blood receiver thereby enabling the blood receiver to receive blood from
10 the cut end of the umbilical cord.

7. Apparatus as in Claim 6 further including clamp means for clamping at least one end of the umbilical cord.

8. An umbilical cord clamping, cutting and blood sampling device comprising

15 a top housing and a bottom housing,

the top housing and bottom housing each having front, back, top, and bottom sides,

the back side of the top housing and back side of the bottom housing being hingedly connected such that
20 the top and bottom housings may be moved from an open position to a closed position, the open position allowing an umbilical cord to be inserted between the top housing and the bottom housing, the closed position enabling holding of at least a portion of an
25 umbilical cord,

a gel disposed on the bottom side of the top housing and the top side of the bottom housing,

a clamp releasably connected to the bottom side of the top housing and the top side of the bottom housing,

30 the clamp having a top arm and a bottom arm,

the top arm and bottom arm having front, back, top, and bottom sides,

the back side of the top arm and back side of the bottom arm being hingedly attached to each other,

the front side of the top arm and the front side of the bottom arm having a mating clamp latch,

a blade having a cutting edge movably connected to the top housing such that when the top and bottom housings are in a closed position for holding an umbilical cord, the blade may move such that the cutting edge moves in a downward direction from a position over the umbilical cord thereby cutting through the umbilical cord, and

at least one vacuum blood collection vial adapted to be connected to the top housing,

the vacuum blood collection vial being sealed for holding a vacuum therein,

the vacuum blood collection vial being positioned such that when the top and bottom housings are in a closed position holding an umbilical cord and the blade is moved to cut through the umbilical cord, the vacuum of the vacuum blood collection vial is in direct communication with a cut surface of the umbilical cord.

9. An umbilical cord clamping, cutting and blood sampling device comprising

a first housing and a second housing,

the first housing and second housing each having front, back, top, and bottom sides,

the first housing and the second housing being connected such that the first and second housings may be moved from an open position to a closed position, the open position allowing an umbilical cord to be inserted between the first housing and the second housing, the closed position enabling holding of at least a portion of an umbilical cord,

a gel disposed on the bottom side of the first housing and the top side of the second housing,

a clamp releasably connected to the bottom side of the first housing and the top side of the second housing,

the clamp having a top arm and a bottom arm,
the top arm and bottom arm having front, back,
top, and bottom sides,

the back side of the top arm and back side of the
5 bottom arm being hingedly attached to each other,

the front side of the top arm and the front side
of the bottom arm having a mating clamp latch,

a blade having a cutting edge movably connected to the
first housing such that when the first and second housings
10 are in a closed position for holding an umbilical cord,
the blade may move such that the cutting edge moves in a
downward direction from a position over the umbilical cord
thereby cutting through the umbilical cord, and

at least one vacuum blood collection vial adapted to
15 be connected to the first housing,

the vacuum blood collection vial being sealed for
holding a vacuum therein,

the vacuum blood collection vial being positioned
such that when the first and second housings are in a
closed position holding an umbilical cord and the
20 blade is moved to cut through the umbilical cord, the
vacuum of the vacuum blood collection vial is in
direct communication with a cut surface of the umbili-
cal cord.

25 10. An apparatus for cutting an umbilical cord and
collecting blood therefrom in a relatively clean manner
comprising

a first housing and a second housing,

the first housing and second housing each having
30 front, back, top, and bottom sides,

the first housing and the second housing being
connected such that the first and second housings may
be moved from an open position to a closed position,
the open position allowing an umbilical cord to be
35 inserted between the first housing and the second

housing, the closed position enabling holding of at least a portion of an umbilical cord, a first gel and a second gel,

5 the first gel disposed on the bottom side of the first housing and the second gel disposed on the top side of the second housing such that when the first and second housings are placed in the closed position around an umbilical cord the first and second gels thereby circumscribe the cord forming a seal around
10 the cord and between the cord and the first and second housings without occluding blood flow through the umbilical cord,

a blade having a cutting edge movably connected to the first housing such that when the first and second housings
15 are in a closed position for holding an umbilical cord, the blade may move such that the cutting edge moves in a downward direction from a position over the umbilical cord thereby cutting through the umbilical cord and creating an orifice providing direct communication with blood in the
20 umbilical cord, and

at least one blood collecting container adapted to be connected to one of the first housing and second housing such that when the first and second housings are in a closed position and the first and second gels form a seal
25 around the umbilical cord and the blade is moved to cut through the umbilical cord thereby creating an orifice, the blood collecting container is in direct liquid communication with the blood in the cord through the orifice such that the blood may be collected in a clean manner.

30 11. Apparatus for providing a seal around an umbilical cord comprising

a first housing and second housing,

the first housing and second housing each having front, back, top, and bottom sides,

35 the first housing and the second housing being

connected such that the first and second housings may be moved from an open position to a closed position, the open position allowing an umbilical cord to be inserted between the first housing and the second housing, the closed position enabling holding of at least a portion of an umbilical cord,
5 a first gel and a second gel,

the first gel disposed on the bottom side of the first housing and the second gel disposed on the top side of the second housing such that when the first and second housings are placed in the closed position around an umbilical cord the first and second gels thereby circumscribe the cord forming a seal around the cord and between the cord and the first and second housings.
10
15

12. Apparatus as in Claim 11 wherein

the first gel and second gel being disposed on the first housing and the second housing to form a seal around the cord and between the cord and the first and second housings without occluding blood flow through the umbilical cord.
20

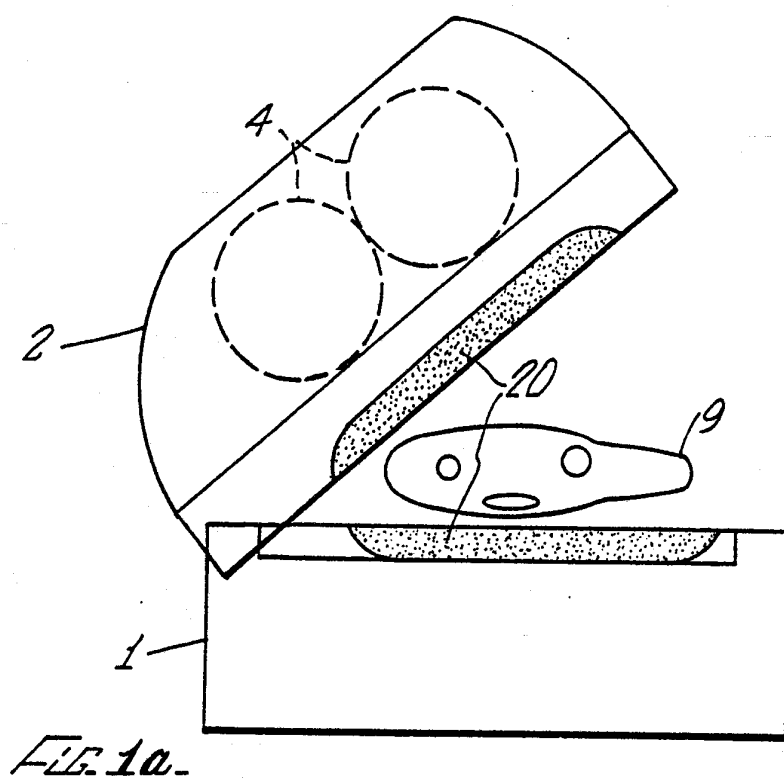
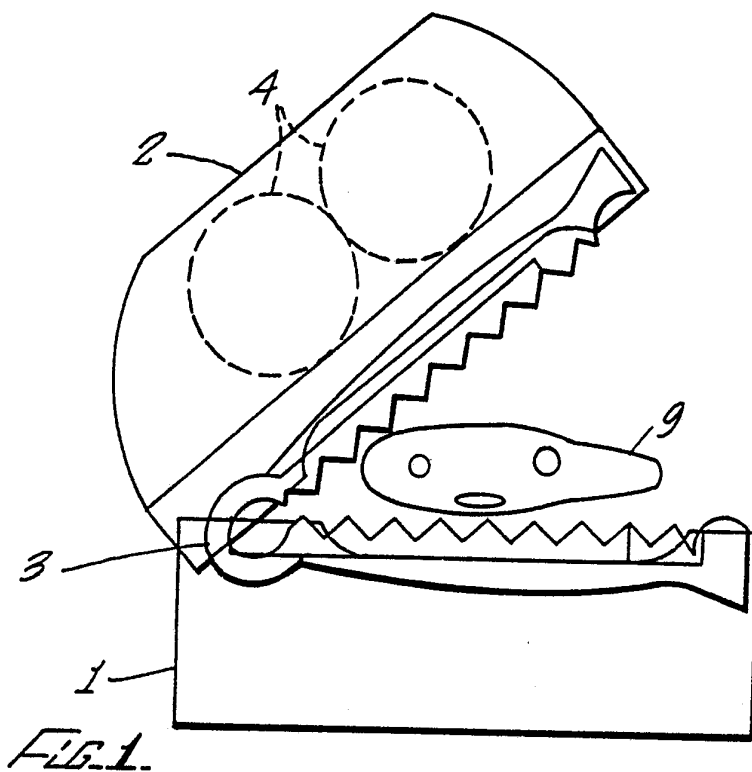
13. Apparatus for cutting an umbilical cord and collecting a blood sample therefrom comprising

a housing for receiving and entrapping a section of umbilical cord,
25

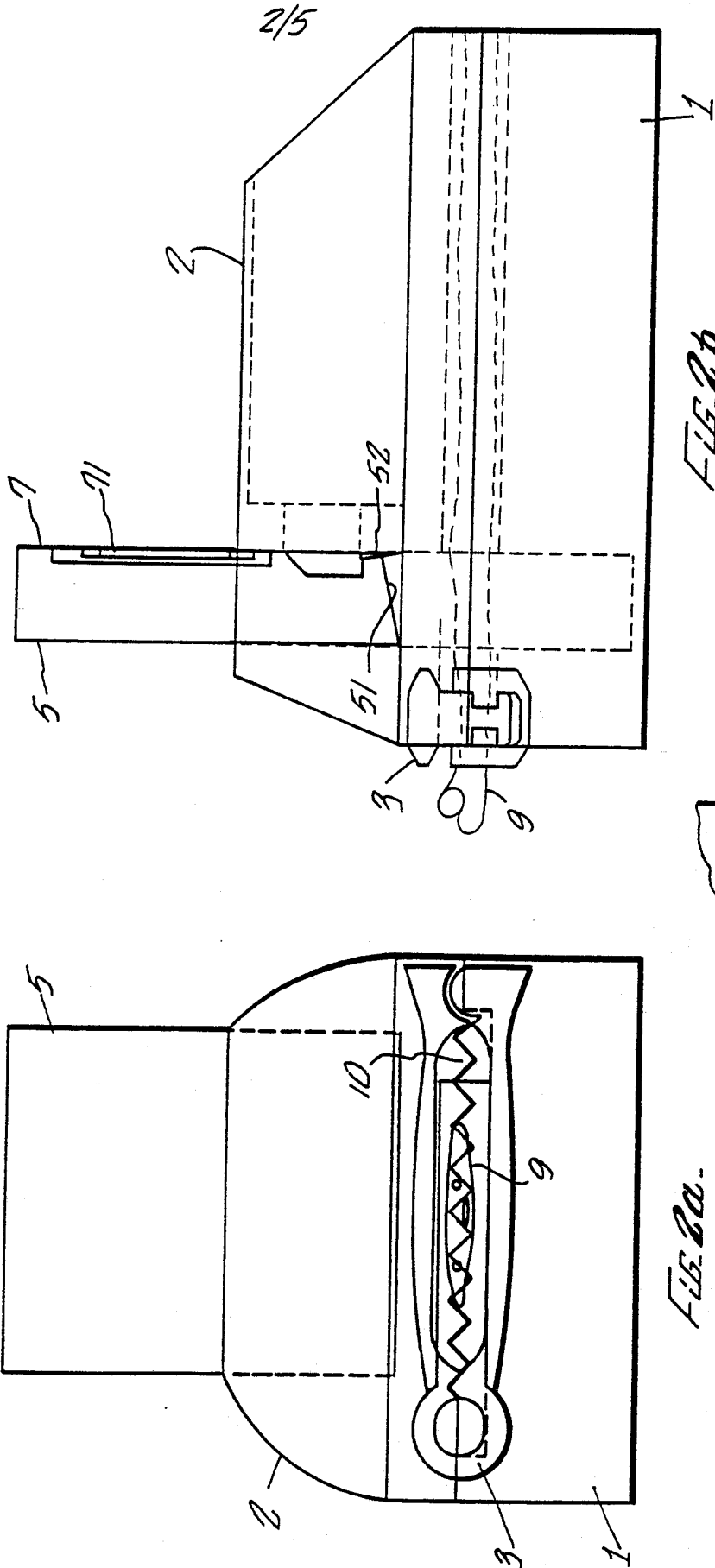
a cutter for cutting an entrapped section of umbilical cord and directing blood contained within the umbilical cord to a blood receiver,

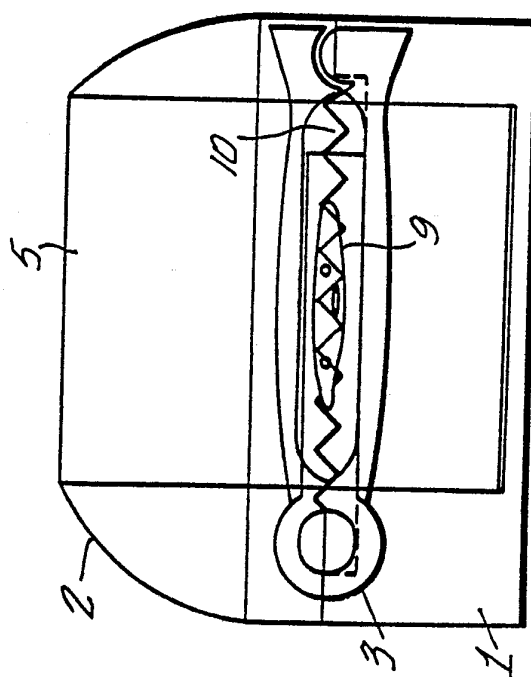
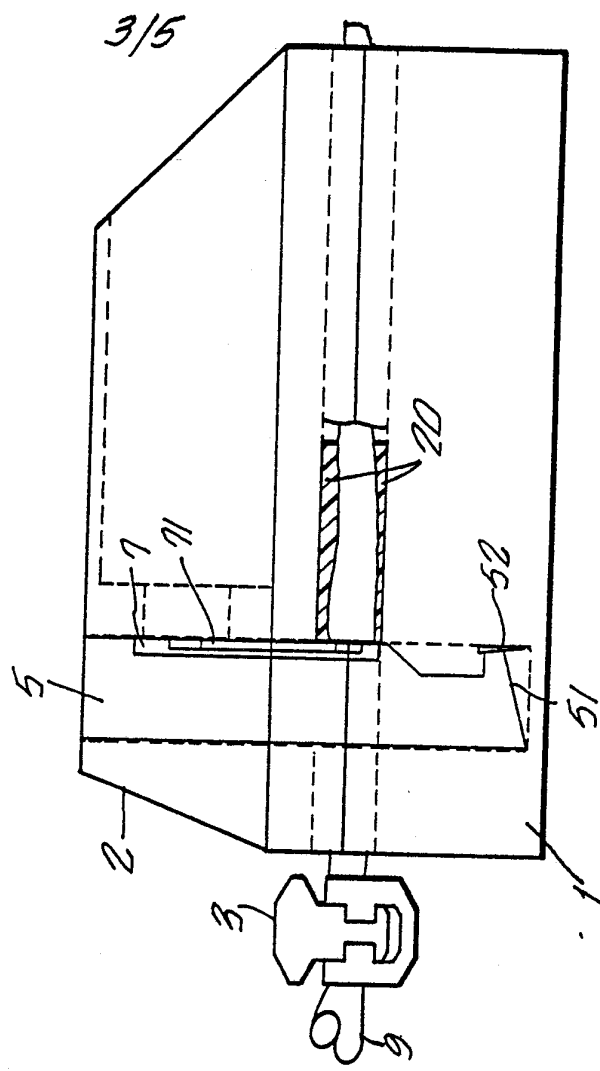
said housing holding said blood receiver and providing fluid communication between the blood within the umbilical cord and the blood receiver thereby enabling the blood receiver to receive blood contained in the umbilical cord in a clean manner.
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SUBSTITUTE SHEET





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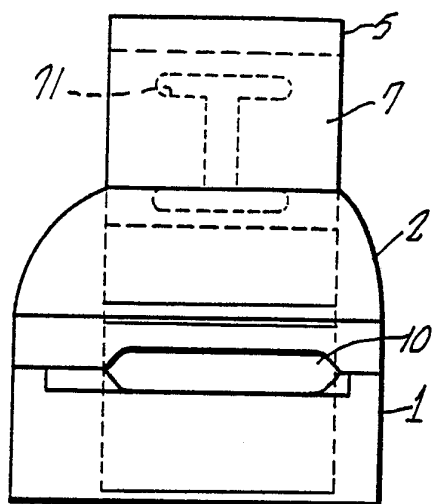


FIG. 4a.

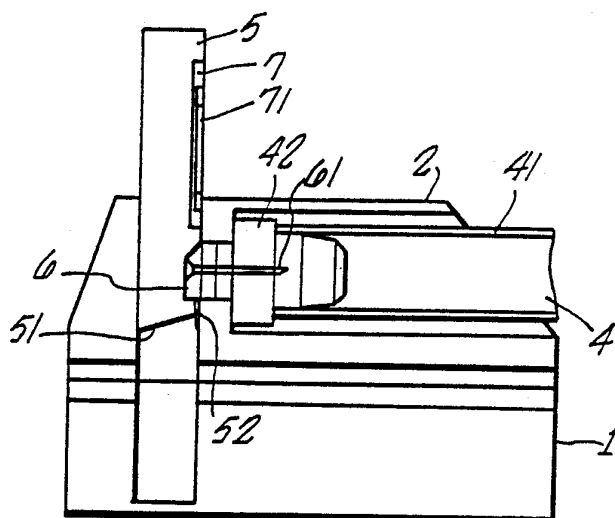


FIG. 4b.

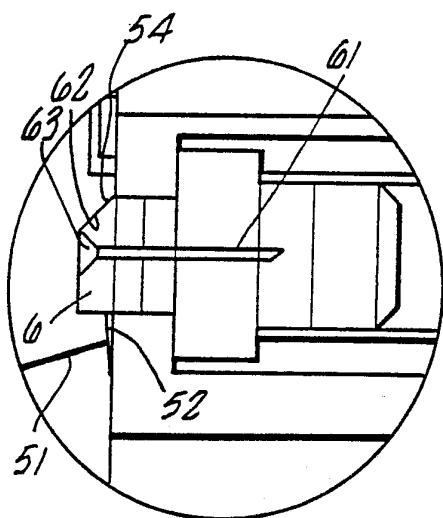


FIG. 4c.

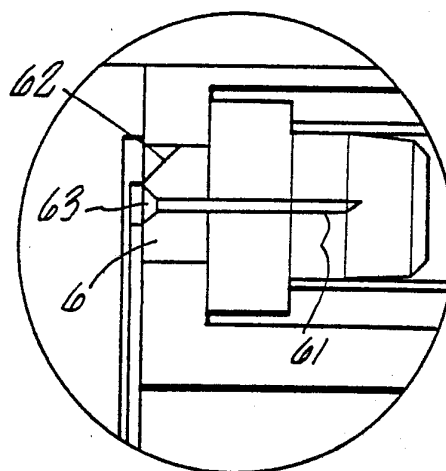


FIG. 4d.

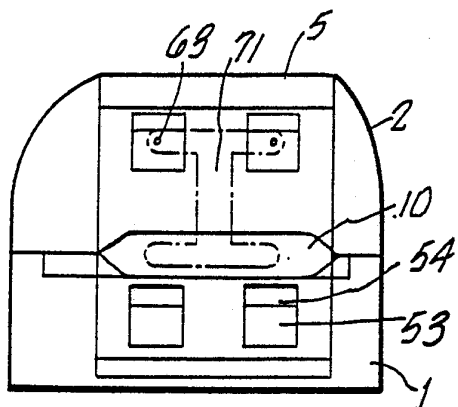


FIG. 4e.

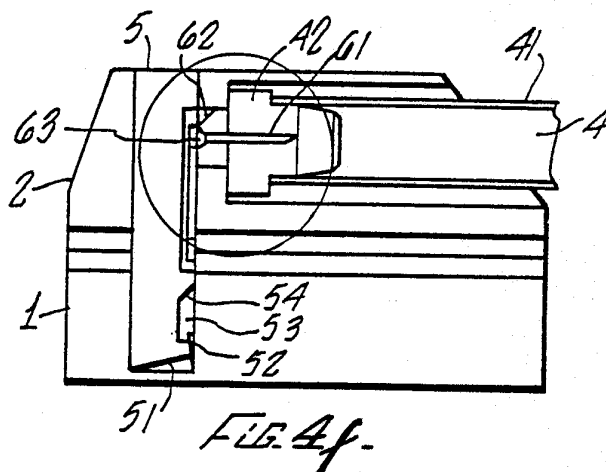
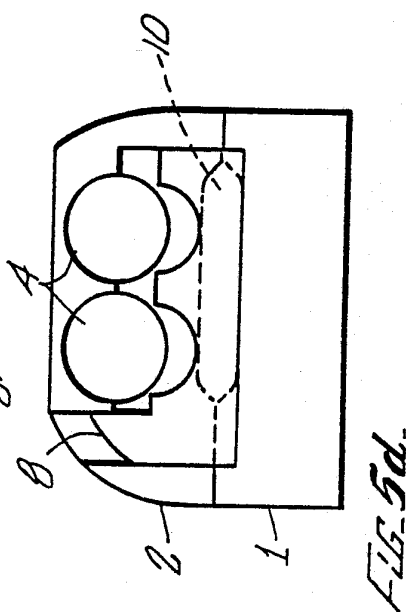
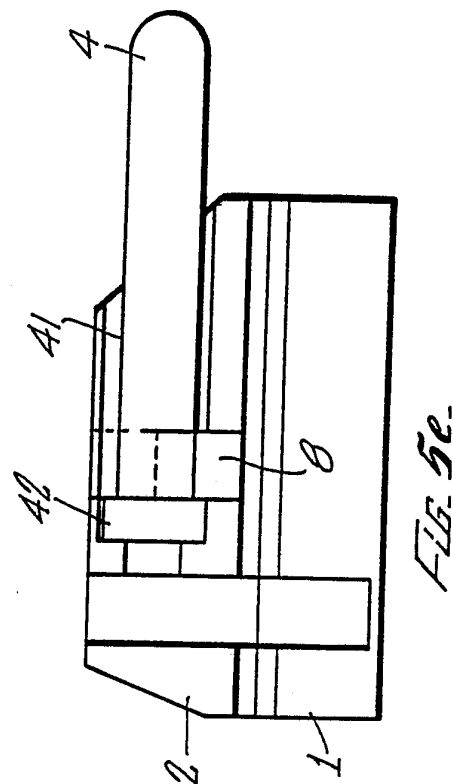
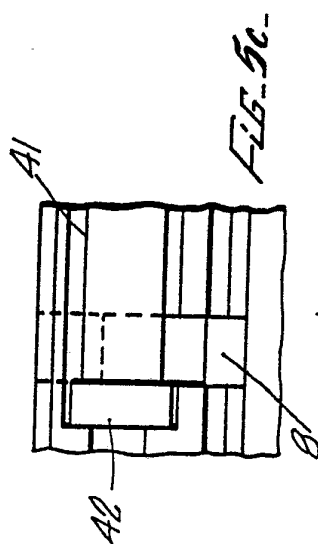
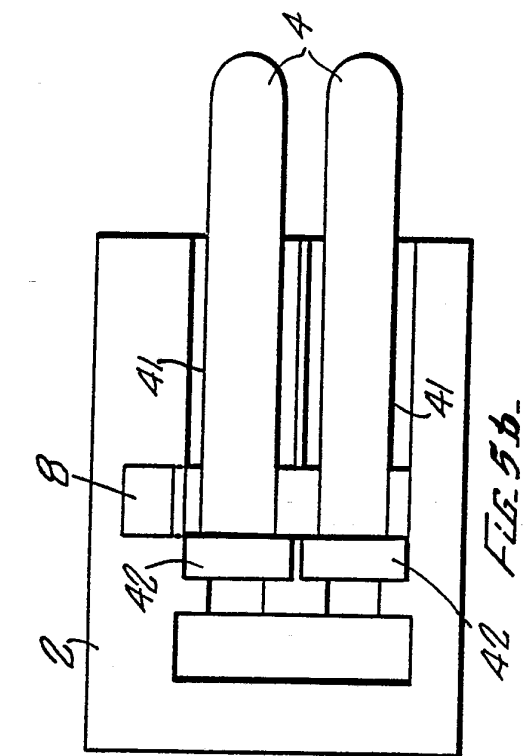


FIG. 4f.

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INTERNATIONAL SEARCH REPORT

International Application No. PCT/US92/02159

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): A61B 17/00		
U.S. Cl: 606/120,174; 604/240; 128/764		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
U.S.	606/120, 167, 174, 205, 208; 604/240; 128/764	
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 ⁹	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
Y	US, A, 4,428,374 (AUBURN) 31 January 1984, See the entire document.	1,2
Y	US, A, 4,938,215 (SCHULMAN) 03 July 1990, See the entire document.	1,2
Y	US, A, 4,716,886 (SCHULMAN) 05 January 1988, See the entire document.	1,2
Y	US, A, 4,781,188 (COLLINS) 01 November 1988, See the entire document.	1,2
A	US, A, 3,807,406 (RAFFERTY) 30 April 1974, See the entire document.	1,2
A	US, A, 4,327,746 (FEASTER) 04 May 1982, See the entire document.	1,2
A	US, A, 4,976,271 (BLAIR) 11 December 1990, See the entire document.	1,2
A	US, A, 4,972,843 (BRODEN) 27 November 1990, See the entire document.	1,2
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>¹⁰ Special categories of cited documents: ¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"A" document member of the same patent family</p> </div> </div>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search		Date of Mailing of this International Search Report
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International Searching Authority		Signature of Authorized Officer
ISA/US		PETER A. ASCHENBRENNER