(19) DANMARK

(10) DK/EP 2910257 T3

(12) Oversættelse af europæisk patentskrift

Patent- og Varemærkestyrelsen

(51) Int.Cl.: *A 61 M 1/02 (2006.01)* *A 61 B 5/15 (2006.01)* *A 61 M 1/00 (2006.01)*

(45) Oversættelsen bekendtgjort den: **2018-08-06**

(80) Dato for Den Europæiske Patentmyndigheds bekendtgørelse om meddelelse af patentet: **2018-05-02**

(86) Europæisk ansøgning nr.: **13848013.2**

(86) Europæisk indleveringsdag: **2013-10-17**

(87) Den europæiske ansøgnings publiceringsdag: **2015-08-26**

(86) International ansøgning nr.: **ES2013070710**

(87) Internationalt publikationsnr.: **WO2014060626**

(30) Prioritet: **2012-10-18 ES 201231607**

(84) Designerede stater: **AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR**

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(54) Benævnelse: **Indretning til udvinding af blod fra moderkage eller navlestreng**

(56) Fremdragne publikationer:
WO-A2-2005/041772
ES-A1- 2 368 083
JP-A- H07 184 991
US-A- 5 059 168
US-A- 5 372 581
US-A- 5 915 384

DESCRIPTION

FIELD OF THE INVENTION

[0001] The invention relates to a device for extracting and collecting blood from the placenta and/or umbilical cord, more specifically to a device based on the collection of this blood by allowing it to fall under gravity in combination with a suction system enabling improvement of the collection process.

BACKGROUND OF THE INVENTION

[0002] In recent years, the discovery of the existence of a high content of stem cells in the umbilical cord and in the placenta has encouraged the development of various systems of extracting and collecting blood contained in these organs in order to store it for subsequent use, either for scientific aims or, if required, to be transplanted into patients suffering from certain congenital or acquired diseases such as immunodeficiencies, cancers or metabolic disorders of deposition.

[0003] For transplantation of blood from the umbilical cord and the placenta to be effective, providing the required therapeutic level in the pathologies to be treated, it is crucially important to obtain a sufficient volume of blood rich in stem cells, requiring at least in the order of 1.5 x 10^7 precursor cells per kg of patient body weight for a successful transplant. Currently, the vast majority of systems for blood extraction from the placenta and the umbilical cord are based on sterilised devices for puncturing the umbilical cord immediately after the expulsion of the neonate, during the minutes before the detachment of the placenta. The blood thus extracted falls under the effect of gravity into the blood collection bag, this bag being kept below the height of the woman who has just given birth, thereby encouraging the falling of the blood. Normally, the bag used includes anticoagulant substances and is kept in motion during the collection process, encouraging the preservation of the blood under optimal conditions.

[0004] Using the method described above, the average volume of blood collected in each delivery is estimated at approximately 120 ml. Although this volume is often sufficient to obtain a stem cell content that is later therapeutically effective, in a not insignificant number of patients this volume does not contain the stem cell content necessary as there are insufficient cell numbers.

[0005] Currently, the state of the art includes some systems for obtaining an increase in the blood extracted and collected from the placenta and the umbilical cord, mainly through pressure systems for aspirating this blood, thereby increasing the volume collected and reducing the collection time. Examples of these types of systems are the devices described in patents WO2005/041772, US5097842, US5059168 and US5575795. These devices include

one or more needles for perforating the umbilical vein and/or placenta, means of collecting the blood such as reservoirs, bags or vacuum containers, and means of aspiration or drainage such as vacuum pumps or peristaltic pumps. In all the references cited above, increasing the amount of blood collected is achieved by replacing the usual method, based on a puncture and subsequent fall under gravity, by a method based exclusively on negative pressure exercised by means of suction or drainage. Japanese publication number JPH07184991 A (1995.07.25) discloses an umbilical blood taking appliance comprising: a juncture to the umbilical cord or the placenta, a manual liquid feeding means having suction and liquid feed functions, a blood taking vessel and a communicating means for connecting this liquid feeding means to the juncture and the blood taking vessel. This communicating member has a three-way stock cock having a selective communicating function to make the liquid feeding means selectively communicate with the juncture or the blood taking vessel. Although the devices are capable of carrying out the purposes for which they were designed, producing an increase in the amount of blood collected, they share a common problem related to their basic design being exclusively based on a suction method. As a consequence of the continuous application of this suction, there is the possibility of inducing the appearance of complications such as the sudden appearance of retroplacental haematoma and, consequently, premature detachment of the placenta before detachment naturally takes place and the maternal homeostasis factors at the time of childbirth can minimise bleeding. This detachment, which may be precipitated by a constant uncontrolled suction action of blood, involves an obvious health risk to the mother.

[0006] It is therefore necessary to develop devices that enable increasing the volume of blood collected from the placenta and the umbilical cord, so that the content of extracted stem cells is sufficient to meet the therapeutic needs and, at the same time, are safe for the mother during the time of delivery, ensuring natural detachment of the placenta without any risk to health.

[0007] The present invention aims to satisfy this need by a device for blood collection that combines the usual system of falling under gravity together with the controlled assistance supplied by a suction system.

[0008] Another advantage of the present invention is that with a design that combines extraction by falling under gravity and extraction by suction, as much blood can be extracted from the umbilical cord as that contained in the placenta by only puncturing the umbilical cord. Not needing to puncture the placenta is especially important as such a puncture normally implies a risk of bacterial contamination that can be avoided with the device described here. Additionally, the possibility of collecting blood from the placenta through a perforation of the umbilical cord makes it possible to carry out blood collection immediately after the expulsion of the neonate without needing to wait for the expulsion of the placenta, which can occur in a time from 5 to 30 minutes after the birth of the neonate, implying an optimisation in the working time of the surgeon and the consequent cost savings.

BRIEF DESCRIPTION OF THE INVENTION

[0009] An object of the present invention is a device for blood collection from the placenta and the umbilical cord that combines collection of blood by falling under gravity and simultaneously a suction system that facilitates this falling.

[0010] This object is achieved by a first preferred embodiment of the invention consisting of a device for blood collection from the placenta and the umbilical cord comprising a means of blood extraction constituted by at least one needle or catheter and at least one tube or cannula through which the extracted blood circulates, this blood falling under the effect of gravity into a means of collection; and where the device also comprises a means of suction that is connected to the tube or cannula and is also connected to the means of blood collection through this tube or cannula. This provides an efficient way to increase the volume of blood collected from the placenta and/or the umbilical cord compared to the devices of the current state of the art, additionally offering a technical solution that enables controlling the pressure for suction of the blood, thus enabling an enormous reduction in the risks derived from excessive applied pressure, or from continuous pressure that is produced by the known devices for blood collection.

[0011] Preferably, the means of blood extraction include at least one needle or catheter and a tube or replacement cannula. In this way there is an exchangeable system directly coupled to the extraction device that can be used in case of need without having to replace any additional element that would imply a delay or complication in the collection process.

[0012] In another preferred embodiment of the present invention, the tube comprises at least one means of closure, for example through clamps or, alternatively, systems of by-pass valves operated either manually or automatically. This provides means of control and retention of the collected blood. In addition to the by-pass valve or clamp, the collection device can also comprise within the system of valves, for example, two- or more way shut-off valves and/or no-return or anti-return valves. This provides a control and retention system for collected blood that enables the optimum configuration of the elements of the device in its collection circuit so that the volume of blood obtained can be maximised, additionally ensuring that the collected blood remains inside the device, without returning to the umbilical cord or to the mother. The point of connection of the means of suction to the tube or cannula is located at a distance of less than 50 % of the maximum length of this tube or cannula from the collection device or bag, being preferably located less than 30 % of the maximum length of the cannula from this bag. In this way, a suitable distance is achieved to ensure both a substantial increase in blood collected and the realisation of a gentle pressure not applied too close to the umbilical cord (which could cause undesirable excessive suction). However, depending on the specific features of the type of blood collection that is being carried out, the position of both the means of suction and the optional means of closure can vary, they being located, for example close to the means of collection. In a preferred embodiment of the present invention, the means of collection contains anticoagulants. These preserve the collected blood under optimal conditions.

[0013] In a preferred embodiment of the present invention, the means of suction can be

operated manually or automatically, preferably by a manually operated syringe. This makes the device adaptable to different functions, depending on the requirements of each collection process.

[0014] In a preferred embodiment of the invention, at least the collection device or bag is sterile and, in a more preferred embodiment, the whole of the collection device with all its components is sterile: needle(s), cannula(s), bag(s), valve(s), means of suction.

[0015] Other characteristics and advantages of the present invention will emerge from the description of the invention that follows, as well as from the embodiment illustrated in the accompanying figure.

DESCRIPTION OF THE FIGURES

[0016]

Figure 1 shows schematically the first preferred embodiment of the device described in the present invention.

Figure 2 shows schematically the second preferred embodiment of the device described in the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0017] In accordance with the invention and according to the embodiments shown in Figures 1 and 2, the device for blood extraction and collection is constituted by at least one means of blood extraction (1) that preferably comprises at least one needle or catheter (2) for puncturing the umbilical vein and/or venous system of the placenta and at least one tube or cannula (3) through which the extracted blood flows. In different embodiments of the present invention it is possible to have more than one tube and needle as a replacement system in case of need. Each tube (3) is connected to at least one means of blood collection (4) that preferably comprises a collection bag, preferably incorporating anticoagulants for preserving the blood. Preferably, this bag is not subjected to prior vacuum.

[0018] The device of the present invention also comprises a means of suction (5) that is preferably constituted by a plunger system, operated manually or automatically. This means of suction is connected to the tube (3) and to the means of collection (4) through this tube (3).

[0019] Preferably, the tube (3) comprises at least one means of closure (6), for example by clamps or, alternatively, a by-pass valve system, operated manually or automatically.

Additionally or alternatively to the by-pass valves, the collection device of the invention can also comprise closure valves of two- or more ways and/or non-return valves, for example, within the valve system. In this way, it is possible to have a device capable of exercising a negative pressure on the blood of the umbilical cord that carries the blood towards the means of suction (5) and that at the same time ensures that the collected blood is later kept inside the device, when the blood is transferred from this means of suction (5) towards the means of collection (4) by applying a positive pressure, reversing the movement of the plunger. In order to encourage non-return of the aspirated blood towards the umbilical cord, it is also possible to apply the means of suction (5) oriented substantially towards the means of collection (4) by, for example, an application route in the form of a "V", arranged in the upper part of the means of collection (4) at the point of entry of this tube or cannula (3) into the means of collection (4) (see Figure 1).

[0020] In an embodiment of the invention, the device or collection bag has in its upper part a zone (7) not to be filled with blood, arranged to house the entry cannula in the form of a "V", coupled to the means of suction (5) and, eventually, with a two- or more way closure or by-pass valve. This zone (7) can be of the same material or a different material from the rest of the device or bag for blood collection. It is preferably made of a material that will allow writing on it the data about the collection, identity of the patient, etc. In this preferred embodiment of the invention, the mentioned zone (7) can allow the sticking of labels with the information referred to above, or can even have them already stuck or printed.

[0021] The point of connection of the means of suction (5) to the tube (3) is located at a distance of less than 50 % of the maximum length of this tube (3) from the means of collection (4) or bag, being preferably located less than 30 % of the maximum length of the tube (3) from said bag, so that a substantial increase in the collected blood is obtained and a gentle pressure can be applied not too close to the umbilical cord. In different embodiments of the invention, depending on the specific characteristics of the type of blood collection being carried out, the position both of the means of suction (5) and of the optional means of closure (6) can vary, they being located, for example, close to the needle, close to the means of collection, in an intermediate region, or in a combination of configurations of these positions of these means (5, 6).

[0022] In the various embodiments of the invention, the blood collection device is preferably sterilized.

[0023] The blood collection procedure using the device of the present invention thus comprises the following stages:

1. a) The umbilical vein and/or venous system of the placenta is punctured with a needle (2). Optionally, the umbilical vein can be punctured to extract the blood contained in the placenta without needing to puncture the latter.
2. b) The means of collection (4) is kept at a height below that of the mother and in constant motion encouraging respectively, the falling of blood under gravity and the

preservation of the blood under optimal conditions.

3. c) The means of suction (5) is used to help the extraction of blood and its falling under gravity through the tube (3) towards said means of suction (5) in a controlled way, applying a sufficiently gentle negative pressure to prevent the risk of detachment of the placenta, the amount of this pressure being estimated at the discretion of the physician, depending on the characteristics of each patient and the circumstances of the delivery.
4. d) After carrying out the collection of a volume of blood towards the means of suction (5), for example until the volume of this means of suction (5) is filled, the pressure is reversed by the operation of the plunger, transferring the volume of blood towards the means of collection (4), where it is kept together with the rest of the volume of blood collected during the entire operation. Optionally, to carry out this step, it is possible to apply means of closure (6) to control the flow of blood from the means of suction (5) to the means of collection (4). These means of closure (6) can be any of those on the market and comprise any of the systems of valves described in the present invention: clamp, by-pass, many-way (at least two-way) valves, non-return valves, etc. The means of closure (6) of Figure 1 can also consist of sealing off by simple folding / unfolding over of the means of collection or bag (4) in an embodiment of the invention in which the means of suction (5) is coupled in a "V" to the tube or cannula (3), in the region of its entry to the means of blood collection (4). The folding over of the means of collection (4) is preferably carried out along the line 8 - 8' in Figure 1.

[0024] By the process described above, it is possible therefore to draw residual blood in the placenta and the umbilical cord that is not accessible by a method based exclusively on falling under gravity. This enables a considerable increase in the volume of blood collected, as shown in the data of Table 1, where the results obtained in a sample of collections carried out with gravity collection bags are compared against the data obtained using the present device. Using the data in this table, it is possible to estimate the average increase in volume to be 51 ml when using the device for blood collection based on gravity plus suction of the present invention compared to the volume collected by the usual methods based on devices of gravity collection only. The best results were obtained with the second preferred embodiment of the invention of Figure 2 (means of suction (5) coupled to the tube or cannula (3), at a short distance, but outside the blood collection device or bag (4)), that showed an average increase in the volume of blood collected over the first preferred embodiment of the invention of Figure 1 (where the means of suction is coupled in a "V" to the tube or cannula (3) in the zone of entry to the means of collection (4)) of at least 10 %.

Table 1

Group	**Collection carried out under gravity alone**	**Collection carried out with the present invention**
Samples	9749	10
Mean (ml)	120.1	158
Standard deviation (ml)	28.96	46.5

Group	Collection carried out under gravity alone	Collection carried out with the present invention
Variance (ml)	838.8	1946.6
Median (ml)	**117**	**168**
95 % confidence interval (ml)	119.5 - 121	125.5- 192.1

[0025] Furthermore, the existence of a means of suction in the device of the invention, that can be operated in a controlled way and designed to support the method of blood extraction and collection under gravity, is able to provide the guarantee that premature detachment of the placenta will not take place, so preventing the risks to the health of the mother that accompany the methods of collection by suction of the current state of the art.

[0026] All the embodiments described for the present invention should not be considered as limiting of other variations in the design or the materials employed in manufacture, provided that these variations do not alter the essence of the invention and the object thereof.

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- WO2005041772A **[0005]**
- US5097842A **[0005]**
- US5059168A **[0005]**
- US5575795A **[0005]**
- JPH07184991A **[0005]**

Patentkrav

1. Indretning til blodopsamling fra moderkagen og / eller navlestrengen, omfattende mindst et middel til blodudvinding (1), der udgøres af mindst en nål eller et kateter (2), og mindst et rør eller en kanyle (3), hvorigennem udvundet blod kan strømme, idet røret eller kanylen (3) er forbundet med mindst et middel til blodopsamling (4), idet blodet udvindes ved at nedfalde i midlet til opsamling (4) under påvirkning af tyngdekraften, og idet indretningen er **kendetegnet ved, at** den yderligere omfatter et sugemiddel (5), der bidrager til udvindingen af blod, hvilket sugemiddel (5) er forbundet med røret eller kanylen (3), og yderligere forbundet med blodopsamlingsmidlet (4) ved røret eller kanylen (3); og **ved, at** forbindelsespunktet mellem sugemidlet (5) og røret eller kanylen (3) er placeret med en afstand på mindre end 50% af kanylens maksimale længde fra opsamlingsmidlet (4).

2. Indretning til blodopsamling ifølge krav 1, hvor midlet til blodudvinding (1) yderligere omfatter mindst en erstatningsnål eller kateter (2) og rør eller kanyle (3).

3. Indretning til blodopsamling ifølge et hvilket som helst af kravene 1 og 2, hvor røret eller kanylen (3) omfatter mindst en anordning (6) til lukning af røret eller kanylen (3).

4. Indretning til blodopsamling ifølge de foregående krav, hvor lukke-anordningen (6) af røret eller kanylen (3) omfatter en eller flere klemmer.

5. Indretning til blodopsamling ifølge et hvilket som helst af kravene 3 og 4, hvor lukkeanordningen (6) af røret eller kanylen (3) omfatter et system af omløbsventiler (6), der betjenes manuelt eller automatisk.

6. Indretning til blodopsamling ifølge krav 3, hvor lukkeanordningen (6) af røret eller kanylen (3) omfatter en eller flere kontraventiler.

7. Indretning til blodopsamling ifølge krav 5, hvor systemet med omløbsventiler (6) omfatter mindst én to-eller-flervejs-ventil.

8. Indretning til blodopsamling ifølge de foregående krav, hvor forbindelsespunktet mellem sugemidlet (5) og røret eller kanylen (3) er placeret med en afstand på mindre end 30% af rørets eller kanylens maksimale længde (4) fra opsamlingsmidlet (4).

9. Indretning til blodopsamling ifølge et hvilket som helst af kravene 1 til 8, hvor sugemidlet (5) er forbundet med røret eller kanylen (3) i en retning, der i det væsentlige er orienteret mod opsamlingsmidlet (4), ved hjælp af en adgangsvej i form af et "V" anbragt i den øvre del af opsamlingsmidlet (4) ved indføringspunktet for røret eller kanylen (3) i opsamlingsmidlet (4).

10. Indretning til blodopsamling ifølge et hvilket som helst af kravene 1 til 9, **kendetegnet ved, at** midlet til opsamling (4) indeholder anti-koagulanter.

11. Indretning til blodopsamling ifølge et hvilket som helst af kravene 1-10 **kendetegnet ved, at** sugemidlet (5) kan betjenes manuelt eller automatisk.

12. Indretning til blodopsamling ifølge krav 11, hvor sugemidlet (5) er en manuelt betjent sprøjte.

13. Indretning til blodopsamling ifølge krav 9, omfattende en lukkeanordning (6) af røret eller kanylen (3), som omfatter foldning / udfoldning af opsamlingsmidlet (4) i området for indføring af sugemidlet (5) og røret eller kanylen (3) i blodopsamlingsmidlet (4).

14. Indretning til blodopsamling ifølge et hvilket som helst af kravene 9 eller 13, omfattende en zone (7) indrettet til at huse indføringskanylen i et "V", idet zonen (7) yderligere er indrettet til at skrive information eller fastklæbe informations-mærker.

DRAWINGS

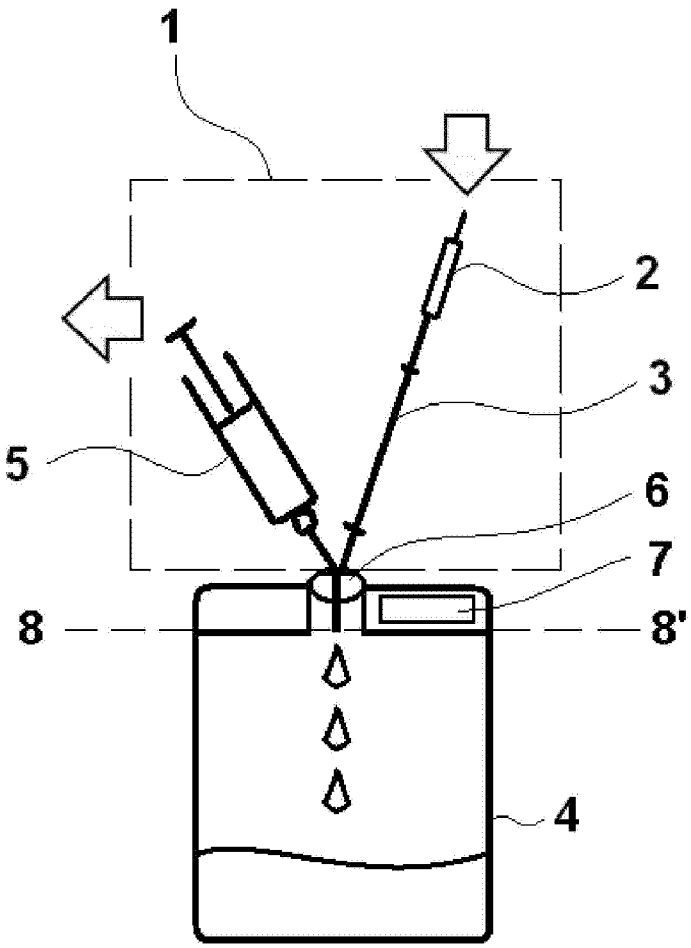

FIG. 1

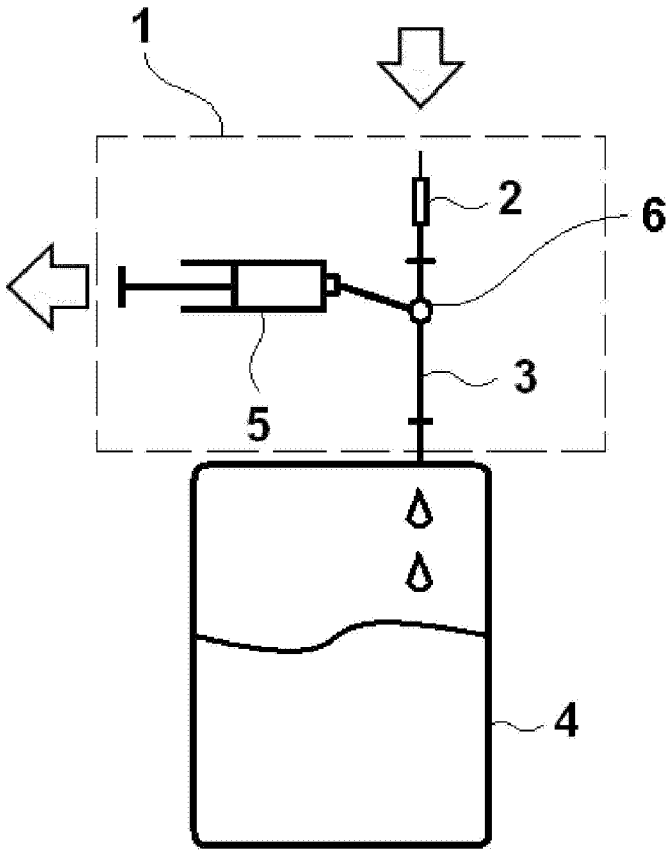

FIG. 2