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(71) Applicant: SG MEDITECH PTE LTD [SG/SG]; 10 Ubi Crescent, Lobby C, #02-41 Ubi Techpark, Singapore 408564 (SG).
(72) Inventors: WIGHT, Ron; c/o Sg MediTech Pte Ltd, 10 Ubi Crescent, #02-41 Ubi Techpark, Lobby C, Singapore 408564 (SG). TAN, Theodore; c/o Sg MediTech Pte Ltd, 10 Ubi Crescent, #02-41 Ubi Techpark, Lobby C, Singapore 408564 (SG). TAN, Gabriel; c/o Sg MediTech Pte Ltd, 10 Ubi Crescent, #02-41 Ubi Techpark, Lobby C, Singapore 408564 (SG). ZHOU, Xiong; c/o Sg MediTech Pte Ltd, 10 Ubi Crescent, #02-41 Ubi Techpark, Lobby C, Singapore 408564 (SG). LEE Chun Siong; c/o Sg MediTech Pte Ltd, 10 Ubi Crescent, #02-41 Ubi Techpark, Lobby C, Singapore 408564 (SG).
(74) Agent: ENGLISH, Matthew; Marks & Clerk Singapore LLP, Tanjong Pagar, P.O. Box 636, Singapore 910816 (SG).

(54) Title: A CANNULATION ASSEMBLY AND METHOD

(57) Abstract: A cannulation assembly comprising: a housing; a needle selectively extendable from a proximal end of said housing; a tube arranged to pass through the housing and through a bore of said needle such that an insertion end of said tube is arranged to selectively project from an insertion end of said needle; a slide mounted to the needle in sliding engagement with the housing and arranged to move the needle from a retracted position to an insertion position such that the needle projects from said housing; wherein said slide is further arranged to move the needle from the insertion position to a locked position such that the needle is fully retracted.

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— with international search report (Art. 21(3))
— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))
A CANNULATION ASSEMBLY AND METHOD

Field of the Invention

The invention relates to the extraction of umbilical cord blood and, in particular, the apparatus and method to achieve this.

Background of Invention

It is well known that umbilical cord blood (UCB) is an increasingly important and rich source of stem cells. It is known that stem cells can divide to create new red blood cells which carry oxygen to the brain, new white blood cells used in the body's immune system and new platelets which can assist in blood clotting. It is currently estimated that stem cells may be used for the treatment of over 45 malignant and non-malignant diseases. Such diseases may include certain cancers such as leukemia, immune and genetic disorders.

UCB may also provide a readily available source of stem cells for transplantation in many situations where bone marrow is currently used. Hence, the use of UCB instead of other sources of stem cells such as for example bone marrow and peripheral blood has many advantages. Such may include for example the reduction or elimination of risk involved in the collection of UCB. UCB is also easier to collect and harvest while avoiding the risks associated with general anesthesia, which is required for the purposes of extracting bone marrow.
UCB is also readily available when needed, assuming an efficient and systematic collection and storage procedure. It has been found that UCB is also more often compatible with people undergoing transplants. Furthermore UCB has a lower procurement cost. It has also been demonstrated that UCB has broader potential clinical applications for improving neural repair, bone and tissue growth. As such, the importance of UCB is now widely recognized. Blood centres worldwide may collect and store UCB after delivery of a baby subject to the parents' consent or request.

However, a problem associated with UCB is that its collection appears to be a one-time possibility and the amount of blood that can be collected is limited using current blood collection technology. Such current blood collection technology may include syringe assisted and gravity assisted methods.

Summary of Invention

In a first aspect the invention provides a cannulation assembly comprising: a housing; a needle selectively extendable from a proximal end of said housing; a tube arranged to pass through the housing and through a bore of said needle such that an insertion end of said tube is arranged to selectively project from an insertion end of said needle; a slide mounted to the needle in sliding engagement with the housing and arranged to move the needle from a retracted position to an insertion position such that the needle projects from said housing; wherein said slide is further arranged to move the needle from the insertion position to a locked position such that the needle is fully retracted.
In a second aspect the invention provides a clamp for clamping an umbilical cord, the clamp comprising: two arms connected by a resilient hinge, said hinge arranged to bias said arms to an open position; one arm having a release lever at an end opposed to the hinge; the second arm having at least one ridge at an end opposed to the hinge; said lever and at least one ridge cooperatively shaped and arranged to engage on closing of said arms and, on activation of the lever, said arms are opened under the resilient biasing of said hinge; wherein said lever is arranged to activate on depressing a contact point on said lever.

In a third aspect the invention provides a cannulation needle comprising a bevel proximate to a tip, said bevel including a reverse curve.

Accordingly, the invention provides for the needle to be used to insert the tube, and can then be removed to allow access for the tube. Further, by passing the tube through the housing, and importantly, through the needle the volume of blood extracted is maximized through having the larger bore of the needle during cannulation.

In one embodiment, the needle may also be locked in place after retraction so as to prevent multiple uses of the cannulation assembly. In this embodiment, the first lock may therefore prevent cross contamination through use with multiple patients.

**Brief Description of Drawings**
It will be convenient to further describe the present invention with respect to the accompanying drawings that illustrate possible arrangements of the invention. Other arrangements of the invention are possible and consequently, the particularity of the accompanying drawings is not to be understood as superseding the generality of the preceding description of the invention.

Figure 1 is an elevation view of a cannulation assembly according to one embodiment of the present invention;

Figure 2 is a sectional view of the cannulation assembly of Figure 1;

Figures 3A and 3B are plan views of the cannulation assembly according to a further embodiment of the present invention;

Figures 4 to 7 are sectional views of the cannulation assembly of Figures 3A and 3B;

Figure 8 provides various views of an umbilical cord clamp according to one embodiment of the present invention;

Figure 9 provides various sectional views of the cannulation assembly of Figure 3A;

Figures 10 and 11 are exploded views of the cannulation assembly of Figure 1.
Figures 12A, 12B, 13A and 13B are isometric views of a cannulation procedure according to one embodiment of the present invention;

Figure 14 is a schematic view of a full cannulation arrangement according to a further embodiment of the present invention;

Figures 15A to 15C are various views of a needle for a cannulation assembly according to a further embodiment of the present invention.

Detailed Description

Figure 1 shows one embodiment where the cannula itself is a length of flexible plastic tubing 4 of suitable composition for the safe transfer and storage of blood. The distal end, or tube insertion end, is spherically tipped 5 whilst the proximal end 6 is connected to the tube set; providing in-utero collection of blood into a removable blood bag 7 and thereafter, redirection and ex-utero collection via a second removable blood bag 8. The cannula slides through the inside diameter of a surgical stainless steel needle 9 or trocar; the push/pull force being characteristic of a transition fit. The needle has a distal taper point, or needle insertion end, 10 (Figure 4 and 5), the proximal end 11 being square and perpendicular and bonded to the carriage tube 13. The length of the needle is sufficient to allow adequate extension 12 from the cannula housing to perforate the umbilical vein. The proximal end of the needle is inserted into the carriage tube 13 which is assembled within a two piece plastic housing, the upper 14a and the lower 14b; suitably bonded together in a manner that prevents disassembly. The carriage tube 13 is guided and
restrained laterally within the lower housing 14b by a combination of ribs 15 and raised projections 16; allowing the carriage to extend and retract with minimal frictional contact. Extending posteriorly with proximal bias from the carriage tube is the carriage lever 17. A slot 18 in the upper housing allows the carriage lever to protrude. In doing so, the carriage is guided linearly and prevented from rotation.

In the as packaged configuration, the spherical tip of the cannula 5 is positioned slightly proximal to the distal opening of the needle, whilst the needle is positioned within the housing; the distal taper point 10 being concealed within the housing. An external adhesive label 19, wraps over the lower to upper housing joint and the carriage lever (Figure 1, 10 and 11). The label maintains the as packaged position of the distal taper point of the needle relative to the housing. It must be peeled off and removed prior to use. Once removed, the cannula shall be considered as used and non-sterile.

Immediately posterior to the label, on the inside of the upper housing 14a and either side of the slot 18, a row of raised projections 20 accommodate two small cylindrical spigots 21 projecting from either side of the carriage lever (Figure 7 and 10). The two rows of raised projections 20, immediately adjacent to the edge of the slot and along the entire length of the slot, present a cylindrical contour 22 with minimal clearance to the outer diameter of the carriage tube 13. When the carriage tube is assembled inside the housing it has a single degree of freedom, able to move linearly i.e. extend and retract. The position of the spigots 21 on the carriage lever 17, relative to the central axis of the needle (and carriage tube), creates a cantilever whose bending moment is a maximum where the carriage lever extends from the carriage tube 23. The opposing force
resisting this bending moment ensures contact between the spigots and each row of raised projections; in a manner similar to a rack and pinion gear. This functionality enables the slider & needle to be selectively temporarily locked in place at any desired position along the length of the feature such that it allows for an inherently stable deployment of the needle in a partially retracted position or partially/fully extended position when the thumb grip is not depressed. Attached to the posterior of the lever, external to the housing, is the thumb grip 24. Pressing the thumb grip disengages the spigots. Held within the palm of the user's hand and with moderate pressure applied to the thumb grip simultaneous with distally biased pressure, the needle extends from the housing; the heel 25 of the lever compressing and clamping the flexible tube to move in unison with the needle. With sufficient extension of the needle, the cannula housing can then be manipulated ready for use together with the cord clamp. The plurality of ridges on the cord clamp are included so as to enable varying clamping force.

The cord clamp 26 is placed over the umbilical cord distal to the desired point of cannulation. It is intended to provide temporary occlusion of the umbilical vein, reducing the potential for blood loss, at that moment when the needle taper point perforates the umbilical vein. The spherical tip 5 of the flexible cannula tubing, having a locally increased outside diameter, creates an annular seal 27 against the inside diameter of the needle (Figure 9); preventing leakage of cord blood past the spherical tip, where it may collect between the outside diameter of the flexible cannula tube and the inside diameter of the needle. Using the quick release lever 28 (Figure 8), the hook 28a rotates locally around a reduced cross section area 28b allowing the cord clamp to be removed...
and repositioned so that the cylindrical aperture 29 in the clamp jaws 30 is aligned with and allowed to clamp the umbilical cord over the needle 9.

Thereafter, the user can grip the cannula housing in one hand whilst guiding the proximal flexible cannula tube 30 through the cannula housing 14 with the other hand; the spherical tip 5 smoothly negotiating the inside of the umbilical vein.

With the flexible cannula sufficiently extended into the umbilical vein, the cord clamp is once again released and then repositioned so that the cylindrical aperture 29 in the clamp jaws 30 is aligned with and allowed to clamp the umbilical cord over the flexible cannula tube 4; the diameter of the cylindrical aperture being sufficiently large to prevent occlusion. Compressing the thumb grip 24 and applying a proximally biased pressure retracts the needle back to the initial position whereupon tactile feedback to the user will suggest resistance to any further retraction. Two (2) spherical protrusions 31 on the inside of the lower housing, posterior to the carriage tube 13, engage with the leading edge of the carriage tube. If the cannula is being used for in-utero collection and immediately thereafter, ex-utero collection, additional proximally biased pressure retracts the needle fully. However, if used for ex-utero this partial retraction creates a needle safe environment for assessing cord blood collection prior to a deliberate re-extension and re-cannulation.

In the partial retraction position, the two (2) spherical protrusions 31 on the lower housing, engage with the leading edge of the carriage tube. By applying sufficient proximal biased pressure to the thumb grip, the leading edge of the carriage will rise
over the spherical projections; which offer a minimal contact area of interference 32 to
the carriage tube. With continued proximally biased pressure all resistance is overcome
and the needle will retract until the carriage lever stops against the proximal extremity of
the slot 18.

There are two methods of preventing the needle from being extended for re-use. Firstly,
two (2) spherical depressions 33 in the carriage tube 13 will align with the
aforementioned spherical projections 31 in the lower housing 14b. The position of
alignment will coincide with the taper point of the needle coming to rest proximal to a
longitudinal rib 34 in the upper housing (Figure 6). Due to the interference of these
spherical protrusions against the carriage tube, combined with resistance to the
compression of the carriage lever creating a moment around the contact point 32 of the
spherical protrusions, the distal taper point now assumes an angular deflection 35
relative to the central axis of the needle i.e. when the needle was extended or partially
retracted. Any attempt to re-extend the needle will result in the needle taper point
colliding with the proximal side of this rib 34. Secondly and further proximally, a
rectangular protrusion 36 from the inside of the lower housing aligns with an anterior
slot 37 in the carriage tube, configured parallel to the centre axis (Figure 5 and 10).
Distally biased pressure applied to the carriage lever 17 will force the proximal end of
this slot 37 against the rectangular protrusion 36, ensuring the carriage remains fully
retracted. With the needle fully retracted and locked, the cannula housing can be slid
over the cannula tube and taped to the umbilical cord as required. In-utero cord blood
collection can proceed followed by ex-utero should it be necessary.
Figures 12A and 12B show the first step for the collection of cord blood. Here at placenta 38 has umbilical cord 42 attached from which the cord blood is to be harvested. A cannulation assembly 44 according to one embodiment of the present invention has the needle 46 extended outside the housing for penetration of the cord. The needle has a bore through which a tube 48 is placed. The tube 48 extends through the housing and through the bore of the needle 46 ready for insertion in the cord.

Figures 13A and 13B show the next step by which the needle having penetrated the cord 42 then allows the tube 48 to be inserted into the cord. The tube 48 is then pushed further into the cord so as to be well within the cord in order for harvesting. The needle is then retracted into the housing and locked in place so as to prevent further use of the cannulation assembly. This then leads to the image shown in Figures 13A and 13B whereby the needle has now been retracted. The tube 48 is inserted into the cord and the cord and indirectly the tube are then clamped by a clamp 49 at the cannulation site 52 so as to hold the tube and cord in place.

Figure 14 shows a possible arrangement of a full cannulation assembly kit. Here, a pair of cannulation assemblies 40 is connected by valves 45 and 50 to supply bags 55. It would be appreciated that in a full arrangement the cannulation assembly 40 will need to drain the harvested blood into a blood bag 55 with Figure 14 showing a full arrangement under optimal conditions. The dual arrangement shown in Figure 14 allows for multiple harvesting points and so accommodates multiple cannulation sites. Further, to ensure that no time is wasted in the critical few minutes from pre-delivery to post-delivery by having multiple blood bags 55 connected to the multiple cannulation assemblies, the
volume of harvested blood can then be maximized. It would be appreciated that such an arrangement may have a single cannulation assembly, a single blood bag, or various combinations thereof. It would further be appreciated that multiple cannulation assemblies, that is, more than two may also be used. Further still, multiple blood bags 55 may also be attached in anticipation of a high supply of cord blood harvested.

Figure 15A to 15C shows a side profile of a needle 65 for a cannula according to one embodiment of the present invention. In this embodiment, the bevel 60 of the needle is a reverse curve having a greater steepness 80 at the middle section of a spline profile. In the present embodiment, the reverse curve is a "S" spline shaped needle bevel design which is designed with a smooth and continuously varying bevel gradient 70, 75. The primary advantage of the proposed design is the shallow proximal tip and reduced bevel length. The advantage of a shallow 90 and narrow proximal needle tip 95 is that it will greatly reduce the initial penetration force required. The reduced bevel length helps to prevent puncturing through the cord as it enables the needle bevel to be fully enclosed by the umbilical cord with minimal depth of insertion of the needle.

The proximal tip 95 of the needle has a shallow gradient 90 (drawn as approximately 14 degrees in Figure 15 for the purposes of a non-limiting example). The mid-section of the bevel has a much steeper gradient 80 (drawn as 48 degrees as a non-limiting example). The final section of the needle bevel resumes to a shallow gradient. The proximal tip 95 is also suitably narrowed (drawn as 60 degree V shaped wedge 100 for the purposes of a non-limiting example).
The steep mid-section creates a tangible increased resistance to insertion such that the operator has a haptic "notch" to indicate that the needle is mid-way into the cord. This will help the operator to differentiate the depth of insertion, and prevent the operator from puncturing right through the cord.
Claims

1. A cannulation assembly comprising
   a housing;
   a needle selectively extendable from a proximal end of said housing;
   a tube arranged to pass through the housing and through a bore of said needle
   such that an insertion end of said tube is arranged to selectively project from an
   insertion end of said needle;
   a slide mounted to the needle in sliding engagement with the housing and
   arranged to move the needle from a retracted position to an insertion position
   such that the needle projects from said housing;
   wherein said slide is further arranged to move the needle from the insertion
   position to a locked position such that the needle is fully retracted.

2. The cannulation assembly according to claim 1, wherein said housing includes a
   first lock arranged to irrevocably lock the needle inside the housing whilst in the
   locked position.

3. The cannulation assembly according to claim 2, wherein the first lock includes
   corresponding lugs on the slide and the housing, said lugs arranged to permit the
   slide to retract into the locked position but prevent the slide from moving from
   the locked position through an interference between the respective lugs.
4. The cannulation assembly according to any one of claims 1 to 3, wherein the needle is arranged to penetrate an umbilical cord, said external diameter of said needle corresponding to the bore of said umbilical cord.

5. The cannulation assembly according to any one of claims 1 to 4, wherein said insertion end of said tube is enlarged so as to seal an interstitial space between the needle bore and tube.

6. The cannulation assembly according to any one of claims 1 to 5, wherein the insertion end is spherical in shape.

7. The cannulation assembly according to any one of claims 2 to 6, wherein said housing includes a second lock intermediate the locked position and the proximal position, said second lock arranged to selectively release the needle on engagement.

8. The cannulation assembly according to any one of claims 1 to 7, wherein a bevel of said needle includes a reverse curve.

9. The cannulation assembly according to claim 8, wherein the reverse curve is a "S" shaped spline.
10. A method of cannulating an umbilical cord comprising the steps of:

- projecting a needle from a housing;
- inserting the needle into the umbilical cord at a cannulation site;
- passing a tube through a bore of said needle;
- projecting the tube from the needle into the umbilical cord;
- retracting the needle into the housing.

11. The method according to claim 10, further including the step, after the retracting step, of clamping the tube at the cannulation site.

12. The method according to claim 10 or 9, further including the step after the retracting step of locking the needle within the housing.

13. A clamp for clamping an umbilical cord, the clamp comprising:

- two arms connected by a resilient hinge, said hinge arranged to bias said arms to an open position;
- one arm having a release lever at an end opposed to the hinge;
- the second arm having at least one ridge at an end opposed to the hinge;
- said lever and at least one ridge cooperatively shaped and arranged to engage on closing of said arms and, on activation of the lever, said arms are opened under the resilient biasing of said hinge;
- wherein said lever is arranged to activate on depressing a contact point on said lever.
14. The clamp according to claim 11, wherein the second arm includes a plurality of ridges spaced so as to provide a varying clamping force to the umbilical cord on engagement of the lever with any one of said ridges.

15. The clamp according to claim 11 or 12, wherein said arms are shaped intermediate the hinge end and opposed ends to form an aperture on closing of said arms.

16. The clamp according to any one of claims 11 to 13, wherein the clamp is molded as a single unit.

17. A cannulation kit comprising a cannulation assembly according to any one of claims 1 to 7 and a clamp according to any one of claims 11 to 14.

18. A cannulation needle comprising a bevel proximate to a tip, said bevel including a reverse curve.

19. The cannulation needle according to claim 18, wherein the reverse curve is an "S" shaped spline.
INTERNATIONAL SEARCH REPORT

International application No.
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A61B 5/15 (2006.01)  A61B 17/34 (2006.01)  A61M 25/06 (2006.01)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

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 practicable, search terms used)

EPDOC & TXTE: (CPC Marks) A61M2202/0462; A61M2202/0464; A61B5/150038; A61B5/150061; A61M2025/0175; A61M25/06/Low, A61B10/0045/LOW, A61B15/0045/LOW, A61M2210/1466, A61M25/065, A61M25/062/Low, A61M2025/081, A61M2025/0001, A61B17/341 5, A61M25/063 1, A61 B5, A61B10, & (Search terms) EXTEND+, RETRACT+, TRANSLAT+, LOCK+, SECUR+, PREVENT+, NEEDLE, CANNULA, HOUSING+ or similar terms; (Applicant & Inventor Search): MEDITECH, WIGHT, TAN, ZHOU, CHUN

Internal Database: Applicant and Inventor Search

MEDLINE: (Search terms) Umbilical blood+, stem cell, placenta, catheter, cannula or similar terms

WPIAP: (IPC Marks) A61M5, A61B5, A61B17, A61D & (Search terms) umbilical+, epidura+, placenta+, needle+, retract+, slid+, translat+

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
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<tr>
<th>Category*</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
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Documents are listed in the continuation of Box C

Further documents are listed in the continuation of Box C

See patent family annex

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"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)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"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
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"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
"&" document member of the same patent family

Date of the actual completion of the international search
10 August 2015

Date of mailing of the international search report
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Name and mailing address of the ISA/AU
AUSTRALIAN PATENT OFFICE
PO BOX 200, WODEN ACT 2606, AUSTRALIA
Email address: pct@ipaustralia.gov.au

Authorised officer
Alina Lacken
AUSTRALIAN PATENT OFFICE
(ISO 9001 Quality Certified Service)
Telephone No. 0262832897

Form PCT/ISA/210 (fifth sheet) (July 2009)
### INTERNATIONAL SEARCH REPORT

#### DOCUMENTS CONSIDERED TO BE RELEVANT

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<td>WO 2013/12106 A1 (SG MEDITECH PTE LTD) 01 August 2013 Figs 13A-13C, 14A; Pages 21-22</td>
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<td>X</td>
<td>US 4627841 A (DORR) 09 December 1986 Figs 1-5; Coin 2, lines 15-36, lines 66-69; Coin 3 lines 4-12</td>
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<td>X</td>
<td>US 8029471 B1 (KHAN-SAHI BZADA et al.) 04 October 2011 Figs: 1, 4, 5; Coin 4 line 20 to coin 5, line 38</td>
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<td>WO 2008/005618 A2 (VASCULAR PATHWAYS, INC) 10 January 2008</td>
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Form PCT/ISA/210 (fifth sheet) (July 2009)
Box No. II  Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
   
   because they relate to subject matter not required to be searched by this Authority, namely:

   the subject matter listed in Rule 39 on which, under Article 17(2)(a)(i), an international search is not required to be carried out, including

2. ☐ Claims Nos.:
   
   because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☑ Claims Nos.:
   
   because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. III  Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See Supplemental Box for Details

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☑ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

   1-4, 10-12

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☒ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☒ No protest accompanied the payment of additional search fees.
Supplemental Box

Continuation of: Box III

This International Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

This Authority has found that there are different inventions based on the following features that separate the claims into distinct groups:

- Claims 1 to 3 are directed to a cannulation device with a selectively extendable needle, a tube over the needle and a slide mounted to the needle. The feature of a lock mechanism is specific to this group of claims.

- Claims 4 and 10 to 12 are directed to cannulation device with a selectively extendable needle, a tube over the needle and a slide mounted to the needle. The feature of a special adaption and use to penetrate an umbilical cord is specific to this group of claims.

- Claims 5 to 6 are directed to cannulation device with a selectively extendable needle, a tube over the needle and a slide mounted to the needle. The feature of an enlarged or spherical end of the tube is specific to this group of claims.

- Claim 7 is directed to cannulation device with a selectively extendable needle, a tube over the needle and a slide mounted to the needle. The feature of a second lock to release the needle is specific to this group of claims.

- Claims 8 to 9 and 18 to 19 are directed to a cannulation needle with a bevel proximate to the tip. The feature of a bevel proximate to a tip, the bevel including a reverse curve is specific to this group of claims.

- Claims 13 to 16 and 17 are directed to a clamp for clamping an umbilical cord. The features of two arms connected by a resilient hinge, the arms having a release lever and ridge opposite the hinge cooperatively shaped and arranged to engage in closing, on activation of the lever (by depressing a contact point on the lever) the arms are opened under the resilient biasing of the hinge, are specific to this group of claims.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

When there is no special technical feature common to all the claimed inventions there is no unity of invention.

In the above groups of claims, the identified features may have the potential to make a contribution over the prior art but are not common to all the claimed inventions and therefore cannot provide the required technical relationship. The only feature common to the first five distinct groups of the claimed inventions (as listed above) and which provides a technical relationship among them is cannulation device with a selectively extendable needle, a tube through the needle and a slide mounted to the needle. However this feature does not make a contribution over the prior art because it is disclosed in documents:

- D1: WO 2013/1 12106 A1 (SG MEDITECH PTE LTD) 01 August 2013

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Therefore in the light of this document this common feature cannot be a special technical feature. Therefore there is no special technical feature common to all the claimed inventions and the requirements for unity of invention are consequently not satisfied a posteriori.

Furthermore there is no common feature between the first five distinct groups of the claimed inventions (as listed above) and the sixth distinct group. Therefore there is no special technical feature common to these claimed inventions and the requirements for unity of invention are consequently not satisfied (for the sixth distinct group) a priori.

The International Searching Authority believes that a search and examination for the second invention will not involve more than negligible additional search and examination effort over that for the first invention and so no additional search fee is required in order to search and examine that invention. However it is considered that the search for the third, fourth, fifth and sixth inventions will require significant additional search and examination effort over that for the first and second inventions, and therefore additional search fees are warranted for these inventions. This search and opinion has been limited to the first and second invention as claimed in claims 1 to 4 and 10 to 12.

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