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(54) FETAL PULSE OXIMETERS AND METHODS OF USING THE SAME

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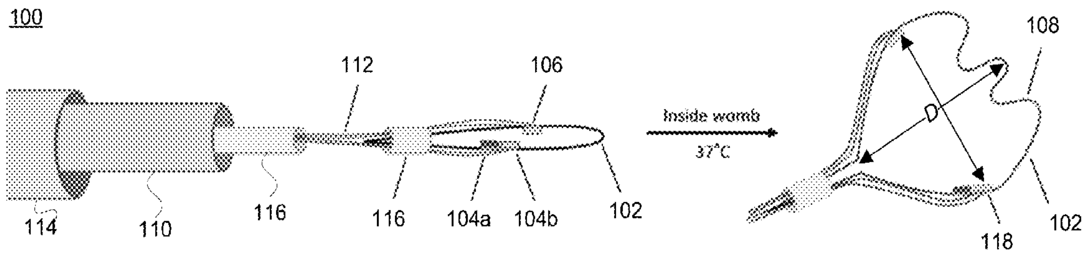
CPC ***A61B 5/00*** (2013.01); ***A61B 5/1464*** (2013.01); ***A61B 5/145*** (2013.01); ***A61B 5/1455*** (2013.01); ***A61B 5/14551*** (2013.01); ***A61B 5/14552*** (2013.01); *A61B 2503/02* (2013.01); *A61B 5/4362* (2013.01)

(57) **ABSTRACT**

One aspect of the invention provides a fetal pulse oximeter including: a shape-memory member adapted and configured to expand outward and define a loop when advanced out of a cannula; one or more light sources mounted on the shape memory member and facing toward a center of the loop, the one or more light sources adapted and configured to generate red and infrared light; and a photodiode mounted on the shape memory member and facing toward a center of the loop. Another aspect of the invention provides a method for measuring recording pulse and blood oxygen saturation. The method includes: advancing the fetal pulse oximeter as described herein out of a cannula within a placenta; allowing the shape-memory member to expand outward; and placing the loop over a limb.



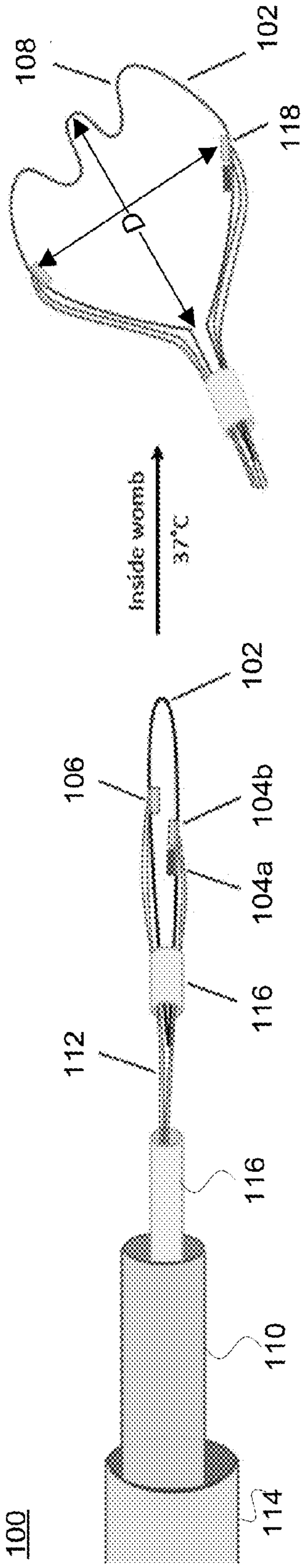

100
114
110
116
112
116
104a
104b
106
102
Inside womb
37°C
108
102
118
D

FIG. 1

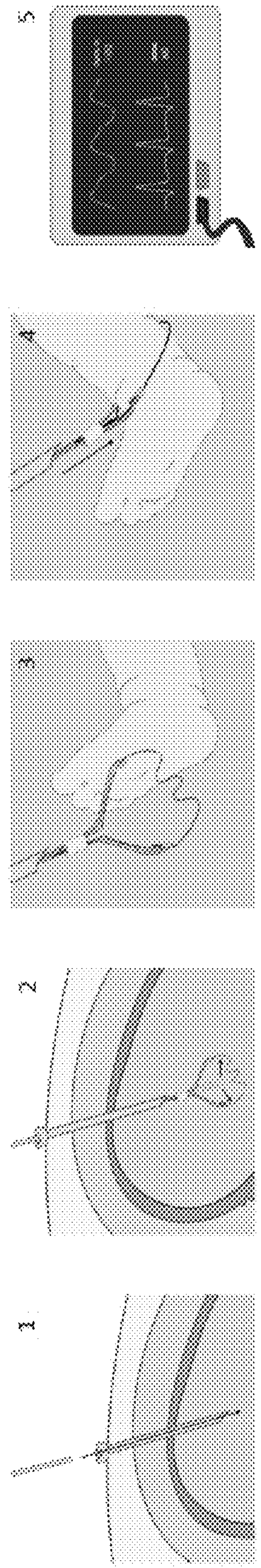

1
2
3
4
5

FIG. 2

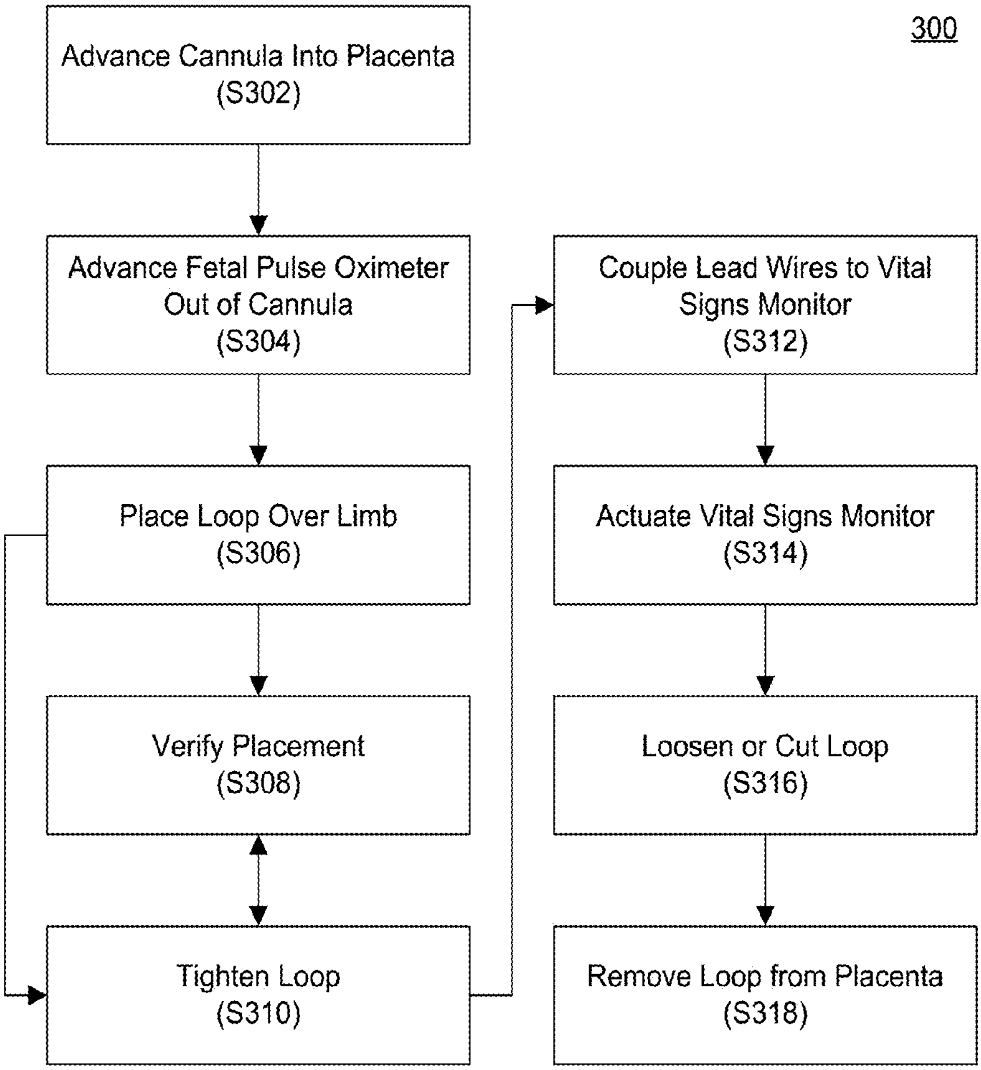

300
Advance Cannula Into Placenta
(S302)
Advance Fetal Pulse Oximeter Out of Cannula
(S304)
Place Loop Over Limb
(S306)
Verify Placement
(S308)
Tighten Loop
(S310)
Couple Lead Wires to Vital Signs Monitor
(S312)
Actuate Vital Signs Monitor
(S314)
Loosen or Cut Loop
(S316)
Remove Loop from Placenta
(S318)

FIG. 3

FETAL PULSE OXIMETERS AND METHODS OF USING THE SAME

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of priority under 35 U.S.C. §119(e) of U.S. Provisional Patent Application Ser. No. 62/321,322, filed Apr. 12, 2016. The entire content of this application is hereby incorporated by reference herein.

BACKGROUND OF THE INVENTION

[0002] Fetuses during fetoscopic surgery can suffer from hypoxia, which can cause permanent organ damage or death. If detected early, hypoxia can easily be addressed by physical or chemical means. However, there is no viable method to monitor oxygen levels of fetuses during fetoscopic surgery. Currently, pulse oximeters are too large (by at least about 50×) to pass through the 3 mm diameter trocar used to gain access to the fetus during the surgery.

SUMMARY OF THE INVENTION

[0003] One aspect of the invention provides a fetal pulse oximeter including: a shape-memory member adapted and configured to expand outward and define a loop when advanced out of a cannula; one or more light sources mounted on the shape memory member and facing toward a center of the loop, the one or more light sources adapted and configured to generate red and infrared light; and a photodiode mounted on the shape memory member and facing toward a center of the loop.

[0004] This aspect of the invention can have a variety of embodiments. The shape-memory member can be adapted and configured to expand to have a sinusoidal region.

[0005] The shape-memory member can exhibit temperature-dependent expansion. The shape-memory member can exhibit temperature-dependent expansion at a temperature between about 20° C. and about 40° C. The shape-memory member can exhibit temperature-dependent expansion at a temperature between about 30° C. and about 37° C. The shape-memory member can exhibit temperature-dependent expansion at a temperature between about 35° C. and about 37° C. The shape-memory member can exhibit temperature-dependent expansion at a temperature of about 37° C.

[0006] The shape-memory member can be nitinol.

[0007] The loop can have a cross-sectional dimension D of between about 1 cm and about 3 cm.

[0008] Another aspect of the invention provides a method for measuring or recording pulse and blood oxygen saturation. The method includes: advancing a fetal pulse oximeter as described herein out of a cannula within a placenta; allowing the shape-memory member to expand outward; and placing the loop over a limb.

[0009] This aspect of the invention can have a variety of embodiments. The method can further include tightening the loop to press the one or more light sources and the photodiode against the surface of the limb.

[0010] The method can further include coupling lead wires from the one or more light sources and the photodiode to a vital signs monitor. The method can further include actuating the vital signs monitor to: selectively actuate the one or more light sources; receive one or more signals from the photodiode; and calculate oxygen saturation (SO_2) as a function of at least the one or more signals received from the photodiode after emission by the one or more light sources. The method can further include loosening the loop. The method can further include cutting the loop. The method can further include removing the loop from the placenta.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] For a fuller understanding of the nature and desired objects of the present invention, reference is made to the following detailed description taken in conjunction with the accompanying drawing figures wherein like reference characters denote corresponding parts throughout the several views.

[0012] FIG. **1** depicts a fetal pulse oximeter according to an embodiment of the invention.

[0013] FIG. **2** depicts a method of measuring pulse and blood oxygen concentration according to an embodiment of the invention.

[0014] FIG. **3** depicts a method for measuring pulse and blood oxygen saturation according to an embodiment of the invention.

DEFINITIONS

[0015] The instant invention is most clearly understood with reference to the following definitions.

[0016] As used herein, the singular form "a," "an," and "the" include plural references unless the context clearly dictates otherwise.

[0017] Unless specifically stated or obvious from context, as used herein, the term "about" is understood as within a range of normal tolerance in the art, for example within 2 standard deviations of the mean. "About" can be understood as within 10%, 9%, 8%, 7%, 6%, 5%, 4%, 3%, 2%, 1%, 0.5%, 0.1%, 0.05%, or 0.01% of the stated value. Unless otherwise clear from context, all numerical values provided herein are modified by the term about.

[0018] As used in the specification and claims, the terms "comprises," "comprising," "containing," "having," and the like can have the meaning ascribed to them in U.S. patent law and can mean "includes," "including," and the like.

[0019] Unless specifically stated or obvious from context, the term "or," as used herein, is understood to be inclusive.

[0020] Ranges provided herein are understood to be shorthand for all of the values within the range. For example, a range of 1 to 50 is understood to include any number, combination of numbers, or sub-range from the group consisting 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, or 50 (as well as fractions thereof unless the context clearly dictates otherwise).

DETAILED DESCRIPTION OF THE INVENTION

[0021] Embodiments of the invention provide fetal pulse oximeters and methods of use thereof.

[0022] Referring now to FIG. **1**, one embodiment of the invention provides a fetal pulse oximeter **100**. The fetal pulse oximeter **100** can include a shape-memory member **102**, one or more light sources **104***a*, **104***b*, and a photodetector **106**.

[0023] The shape-memory member **102** can be adapted and configured to expand to define an internal opening sufficient to encircle a fetal limb (e.g., an arm or a leg). The shape-memory member **102** can expand to a variety of profiles (e.g., a substantially circular profile). For example, the shape-memory member **102** can be adapted and configured to expand to accommodate a cross-sectional dimension D of between about 1 cm and about 3 cm.

[0024] Shape-memory member **102** can be fabricated from a variety of materials such as shape-memory alloys such as nickel-titanium alloys (colloquially known as "nitinol"). Other exemplary shape-memory alloys include Ag—Cd, Au—Cd, Cu—Al—Ni, Cu—Sn, Cu—Zn, Cu—Zn—X (X=Si, Al, Sn), Fe—Pt, Mn—Cu, Fe—Mn—Si, Co—Ni—Al, Co—Ni—Ga, Ni—Fe—Ga, Ti—Nb, Ni—Ti—Hf, Ni—Ti—Pd, and Ni—Mn—Ga.

[0025] The shape-memory member **102** can have a one-way memory effect and expand to the desired dimensions at a variety of temperatures (e.g., room temperature) or have a two-way memory effect and exhibit temperature-dependent expansion (e.g., at a temperature typically found in the womb such as about 37° C.). In one embodiment, the shape-memory member **102** is adapted and configured to change from a folded arrangement shown on the left of FIG. **1** to looped arrangement as shown in the right of FIG. **1**. Such a transformation can be facilitated by the configuration of a central region **108** to take on a sinusoidal shape upon deployment within the womb. Shape-memory member **102** can be bound or coupled to form a closed loop as depicted in FIG. **1** or can be open.

[0026] The sinusoidal-shaped central region **108** can provide visual feedback (e.g., through imaging modalities such as ultrasound) to a user to prevent overtightening of the collar, shape-memory member **102**, which would cause the sinusoidal-shaped central region **108** to straighten.

[0027] In one embodiment, a 20 cm length of body temperature nitinol is shaped in a sinusoidal pattern along an arc of diameter 5 cm. Body temperature nitinol has an Active A(f) temperature—specifying the completion of the shape recovery transformation upon heating—between about 20° C. and about 40° C. (±5° C.) and is available from Johnson Matthey of West Chester, Pa.

[0028] The shape-memory member **102** can serve as a scaffold along which other components such as light sources **104***a*, **104***b* and photodetector **106** can be mounted. Mounting can occur through mechanical fasteners (e.g., staples), chemical fasteners (e.g., adhesives), soldering, and the like.

[0029] Light sources **104***a*, **104***b* can be adapted and configured to produce both red and infrared wavelengths of light. For example, the light sources **104***a*, **104***b* can produce red light having a wavelength of between about 600 nm and about 750 nm (e.g., about 650 mm, about 660 nm, and the like) and infrared light having a wavelength of about 850 mm and about 1,000 nm (e.g., about 900 nm, about 910 nm, about 940 nm, about 950 mm, and the like). Other suitable LED wavelengths are described in John TB Moyle, *Pulse Oximetry* 16-21 (2d ed. 2002).

[0030] Light sources **104***a*, **104***b* can be separate light sources. Alternatively, a single light source can provide light at both red and infrared wavelengths (e.g., through the use of filters). If separate, light sources **104***a*, **104***b* are preferably proximate or adjacent to each other so that the optical path from light sources **104***a*, **104***b* to photodetector **106** is substantially similar (e.g., in length and/or angle).

[0031] Light sources **104***a*, **104***b* can be any device capable of producing the desired wavelengths, fitting within a cannula **110**, and operating within a womb. Suitable light sources include light-emitting diodes (LEDs) such as 0805 LEDs available from sources such as OSRAM Opto Semiconductors Inc. of Sunnyvale, Calif. Such 0805 LEDs have a length of about 2 mm, a width of about 1.25 mm, and a height of about 0.8 mm.

[0032] Photodetector **106** can be arranged on an opposite (e.g., diametrically opposite) side of the shape-memory member **102** in order to measure red and infrared light passing through the fetal limb held within the shape-memory member **102**. Various sizes of fetal pulse oximeter **100** can be produced in order to accommodate limbs of various sizes so that light sources **104***a*, **104***b* and photodetector **106** will be positioned on opposite sides of various size limbs. In another embodiment, a fetal pulse oximeter **100** can include an array of photodetectors **106** so that a well-positioned photodetector **106** (e.g., a photodetector **106** located on an opposite side of the limb from light sources **104***a*, **104***b*) can be selected and monitored after placement over the limb.

[0033] Although photodetector **106** is depicted on an opposite side of the shape-memory member **102** from light sources **104***a*, **104***b*, embodiments of the invention can also implement reflectance and/or transflectance pulse oximetry in which the light sources **104***a*, **104***b* and the photodetector **106** are on the same side of the limb, as illustrated in U.S. Pat. Nos. 6,763,256, 8,818,476, and 9,314,197.

[0034] Photodetector **106** can be a photodiode such as an 0805 photodiode such as the TEMD7000X01 available from Vishay Semiconductors of Malvern, Pa.

[0035] Light sources **104***a*, **104***b* and/or photodetector **106** can be mounted directly to the shape-memory member **102** or can be mounted via a substrate such as a printed circuit board (PCB) such as a flexible PCB **118**. Flexible PCB materials are available from sources such as Flexible Circuit Technologies, Inc. of Minneapolis, Minn. In one embodiment, a piece of 3 mm×2.5 mm flexible printed circuit board is used to mount each of light sources **104***a*, **104***b* and photodetector **106**.

[0036] Light sources **104***a*, **104***b* and photodetector **106** can be powered and/or communicate via one or more wires **112**. For example, a first pair of wires (e.g., 32-gauge wires) can power light sources **104***a*, **104***b* and a second pair of wires (e.g., 32-gauge wires) can power and/or transmit measured values from photodetector **106**.

[0037] As seen in the left of FIG. **1**, the fetal pulse oximeter **100** can be packed flat to fit to fit within a cannula **110**. For example, cannula **110** can have a 3 mm inner diameter, and the fetal pulse oximeter **100** can have a width of about 2.5 mm and a folded height of about 2.1 mm.

[0038] Referring now to FIGS. **2** and **3**, cannula **110** can be placed within a trocar **114** for placement within a placenta. After accessing the placenta (S**302**) in FIG. **2**, Panel **1**, a pusher cannula **116** can advance the folded fetal pulse oximeter **100** beyond the trocar **114** (S**304**). In FIG. **2**, Panel **2**, the shape-memory member **102** expands to define a loop as seen in FIG. **2**, Panel **3**. In FIG. **2**, Panel **4** the loop is placed over a limb (e.g., an ankle) (S**306**), for example, using various imaging modalities such as endoscopy, fetoscopy, ultrasound, and the like (S**308**). Pusher cannula **116** can advance a collar **118** to tighten the shape-memory member **102** such that the light sources **104***a*, **104***b* and photodetector **106** press against the limb (S**310**). A compression spring can be included on either side of collar **118** to provide tactile feedback regarding tension applied to the shape-memory member **102**. Collar **118** can be sized and/or include a camming or ratcheting device to retain the collar **118** after advancement. In FIG. **2**, Panel **5**, the wires **112** can be coupled to one or devices for monitoring, displaying, and/or recording pulse and blood oxygen concentration, e.g., using a DB9 connector (S**312**, S**314**). Suitable devices include vital sign monitors such as those available from Welch-Allyn of Skaneateles Falls, N.Y. Trocar **114**, cannula **110**, and/or pusher cannula **116** can be optionally removed by sliding each cylinder back over wires **114** before the wires are coupled to a monitoring device.

[0039] Embodiments of the invention can be used as a blood oxygen monitor for fetuses during minimally invasive fetal surgery. A pulse oximeter **100** can loop around the fetal extremity at the beginning of the procedure and remain in place throughout, notifying surgeons if fetal blood oxygenation level falls below the normal range, and allowing them to enact emergency procedures accordingly. Once the procedure is complete, the device **100** can easily be loosened and looped off or cut off (S**316**) using standard fetoscopic forceps and scissors and withdrawn from the placenta (S**318**), e.g., by withdrawal through cannula **110**.

EQUIVALENTS

[0040] Although preferred embodiments of the invention have been described using specific terms, such description is for illustrative purposes only, and it is to be understood that changes and variations may be made without departing from the spirit or scope of the following claims.

INCORPORATION BY REFERENCE

[0041] The entire contents of all patents, published patent applications, and other references cited herein are hereby expressly incorporated herein in their entireties by reference.

1. A fetal pulse oximeter comprising:
   - a shape-memory member adapted and configured to expand outward and define a loop when advanced out of a cannula;
   - one or more light sources mounted on the shape memory member and facing toward a center of the loop, the one or more light sources adapted and configured to generate red and infrared light; and
   - a photodiode mounted on the shape memory member and facing toward a center of the loop.

2. The fetal pulse oximeter of claim **1**, wherein the shape-memory member is adapted and configured to expand to have a sinusoidal region.

3. The fetal pulse oximeter of claim **1**, wherein the shape-memory member exhibits temperature-dependent expansion.

4. The fetal pulse oximeter of claim **1**, wherein the shape-memory member exhibits temperature-dependent expansion at a temperature between about 20° C. and about 40° C.

5. The fetal pulse oximeter of claim **1**, wherein the shape-memory member exhibits temperature-dependent expansion at a temperature between about 30° C. and about 37° C.

6. The fetal pulse oximeter of claim **1**, wherein the shape-memory member exhibits temperature-dependent expansion at a temperature between about 35° C. and about 37° C.

7. The fetal pulse oximeter of claim **1**, wherein the shape-memory member exhibits temperature-dependent expansion at a temperature of about 37° C.

8. The fetal pulse oximeter of claim **1**, wherein the shape-memory member is nitinol.

9. The fetal pulse oximeter of claim **1**, wherein the loop has a cross-sectional dimension D of between about 1 cm and about 3 cm.

10. A method for measuring or recording pulse and blood oxygen saturation, the method comprising:
   - advancing the fetal pulse oximeter of claim **1** out of a cannula within a placenta;
   - allowing the shape-memory member to expand outward; and
   - placing the loop over a limb.

11. The method of claim **10**, further comprising:
   - tightening the loop to press the one or more light sources and the photodiode against the surface of the limb.

12. The method of claim **10**, further comprising:
   - coupling lead wires from the one or more light sources and the photodiode to a vital signs monitor.

13. The method of claim **12**, further comprising:
   - actuating the vital signs monitor to:
     - selectively actuate the one or more light sources;
     - receive one or more signals from the photodiode; and
     - calculate oxygen saturation (SO_2) as a function of at least the one or more signals received from the photodiode after emission by the one or more light sources.

14. The method of claim **10**, further comprising:
   - loosening the loop.

15. The method of claim **10**, further comprising:
   - cutting the loop.

16. The method of claim **10**, further comprising:
   - removing the loop from the placenta.

* * * * *

专利名称(译)	胎儿脉搏血氧计及其使用方法		
公开(公告)号	US20170290510A1	公开(公告)日	2017-10-12
申请号	US15/477648	申请日	2017-04-03
[标]申请(专利权)人(译)	贝勒医学院		
申请(专利权)人(译)	贝勒医学院的医学		
当前申请(专利权)人(译)	贝勒医学院的医学		
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IPC分类号	A61B5/00 A61B5/145 A61B5/1455 A61B5/1464		
CPC分类号	A61B5/00 A61B5/1464 A61B5/145 A61B5/4362 A61B5/14551 A61B5/14552 A61B2503/02 A61B5/1455 A61B5/02411 A61B5/02427 A61B5/6875		
优先权	62/321322 2016-04-12 US		
外部链接	Espacenet USPTO		

摘要(译)

本发明的一个方面提供了一种胎儿脉搏血氧计，包括：形状记忆构件，其适于并构造成在向外伸出套管时向外扩展并限定环;一个或多个光源安装在形状记忆构件上并面向环的中心，所述一个或多个光源适于并配置成产生红光和红外光;光电二极管安装在形状记忆构件上并面向环的中心。本发明的另一方面提供了一种用于测量记录脉冲和血氧饱和度的方法。该方法包括：将如本文所述的胎儿脉搏血氧计推出胎盘内的套管;允许形状记忆构件向外扩展;并将环放在肢体上。