

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISIÓN DE NUEVAS CREACIONES

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Abogado
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(Apoderado)

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



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Radicación	03 - 98 776
Trámite	003
Evento	001
Actuación	430
Oficio	8290
Folios	010

Patente de Invención ☐ Patente de Modelo de Utilidad ☒

Como resultado del examen de fondo, realizado con fundamento en el artículo 85 en concordancia con los artículos 45 y 48 de la Decisión 486 de la Comisión de la Comunidad Andina, se le comunica:

1. De los documentos estudiados

- 1.1. Descripción: Folios 5 a 7 como se radicó inicialmente
- 1.2. Reivindicaciones: Folios 7 a 13 como se radicó inicialmente
- 1.3. Dibujos: Folios 14 a 20 como se radicó inicialmente

2. Del objeto de la solicitud

- Título de la solicitud: *Dispositivo balón coil para la oclusión del ductus arterioso persistente*, folio 1. (Ver observaciones en el punto 3.1, adelante)
- El objeto de la presente solicitud de patente de modelo de utilidad consiste en suministrar un dispositivo que cierra el paso de sangre de la aorta a la arteria pulmonar a través del *ductus arteriosus*, que es un conducto formado entre la vena pulmonar y la arteria aorta en la etapa fetal del cuerpo humano y que no desaparece después del nacimiento (es persistente). El dispositivo se puede instalar por cateterismo, o sea, por introducción a través de un conducto sanguíneo (venoso) y no requiere cirugía.

El problema planteado en esta solicitud es lograr ocluir el ductus arteriosus persistente en los casos en éste que tiene un diámetro mínimo mayor de 5 mm, cuando, convencionalmente, se emplearía la cirugía para lograrlo.

Para solucionar este problema técnico la solicitud en estudio proporciona un dispositivo que incluye un resorte en espiral y un elemento inflable (globo), que

se ubican en una posición intermedia del ductus, donde se infla el globo para producir el cierre del paso de sangre por el ductus, adaptándose a la forma interior de dicho ductus.

Reivindicaciones 1 a 8: Un dispositivo, para la oclusión del ductus arteriosus persistente cuyo diámetro mínimo es igual o mayor de 5 mm , mediante técnicas de cateterismo, caracterizado porque consta de: una unidad liberable y una unidad posicionadora.

La Clasificación Internacional de Patentes (IPC) asignada es: A61M 25/04, 25/10

3. De la solicitud de Patente de Modelo de Utilidad

3.1 De la descripción (artículo 28 D. 486)

Durante el análisis del texto de la descripción y de las ilustraciones anexadas, se observaron los siguientes defectos:

- 1) El título o nombre del modelo contiene el término *coil* que no se encuentra en el Diccionario de la Real Academia Española (DRAE). Se sugiere sustituirlo por la expresión que utiliza el solicitante en el folio 6 (*espiral de resorte*) o, mejor, por *alambre en espiral*.
- 2) El título o nombre del modelo no concuerda completamente con lo que se reclama en el capítulo reivindicatorio.
- 3) El título o nombre del modelo contiene el término *balón* cuyo significado, según el DRAE, no concuerda con el contexto. Este mismo término se emplea a lo largo de la solicitud, donde también es objetado. Se sugiere sustituirlo por *globo* u otra expresión que defina mejor lo que se divulga en la solicitud.
- 4) El título o nombre del modelo contiene la expresión *ductus arterioso* que es una combinación no admisible de *ductus arteriosus* (expresión científica, en latín, admisible) con *ducto* (o *conducto*) *arterioso*, que sería la traducción al español. Esta misma expresión objetada se encuentra a lo largo de la solicitud.
- 5) Las páginas destinadas a la especificación (esto es, la descripción y las reivindicaciones) del objeto de la solicitud contienen membretes, lo que no es admisible porque la información contenida en ellos no contribuye a la divulgación del objeto de la solicitud.
- 6) El capítulo descriptivo no se encuentra paginado consecutivamente, por lo que se dificulta realizar las referencias al texto.
- 7) Dentro del capítulo descriptivo no se encuentra un apartado dedicado a las figuras o dibujos que lo acompañan, donde se enumere y defina lo que se ilustra en ellas.
- 8) La descripción no es completa, no detalla muchas de las características reclamadas en el capítulo reivindicatorio.
- 9) El párrafo titulado *Estado de la técnica desventajas* (¿?), en el folio 6, es contradictorio.
- 10) Las figuras no fueron realizadas siguiendo las reglas del dibujo técnico y por tanto no son claras.
- 11) Algunas de las figuras contienen letreros superfluos, que no contribuyen a aclarar ningún aspecto del objeto de la solicitud o que se refieren a algo evidente, y, en cambio, ninguna de las figuras contiene números o signos de referencia que señalen a las partes, piezas, componentes, elementos o aspectos ilustrados. Se sugiere consultar las figuras de los documentos citados adelante como anterioridades.
- 12) En el folio 7 aparece la expresión *Un dispositivo conformado por una unidad liberable y una unidad posicionadora ... el dispositivo es introducible,*

inflable, liberable e implantable mediante técnicas de cateterismo. Lo que significa que la *unidad posicionadora* -junto con la *unidad liberable*- tiene todas las características mencionadas, lo cual no es evidente.

- La descripción no cumple con los requisitos de claridad y de completitud que exige el Art. 28 de la Decisión 486.

3.2 De las Reivindicaciones (artículo 30 D 486)

Durante el análisis del texto de las reivindicaciones se observaron los siguientes defectos:

- 1) Las reivindicaciones, folios 7 a 13, no se encuentran numeradas individual y consecutivamente.
- 2) Las reivindicaciones contienen títulos individuales que afectan negativamente la concisión.
- 3) En las reivindicaciones aparece la expresión *ductus arterioso* que fue objetada arriba, en el punto 3.1 (4)
- 4) Lo análogo es aplicable al término *coil* y al término *balón* que se encuentran en algunas reivindicaciones.
- 5) Lo reclamado en las reivindicaciones 2ª a 17ª -numeradas por el solicitante como 1.1 a 2.8 (¿?)-, folios 7 a 13, carece de soporte, porque lo allí reclamado no ha sido previamente detallado dentro del capítulo descriptivo.
- 6) Lo esencial de lo reclamado en la reivindicación 5ª -numerada como 1.4-, folio 9, es redundante con respecto a lo reclamado en la reivindicación 2ª -numerada como 1.1-. Los aspectos no contemplados en la segunda reivindicación se refieren a cuestiones que no definen el dispositivo reclamado, no son tangibles, y por tanto no pueden caracterizar un producto concreto, no lo pueden definir para los fines de la propiedad industrial.
- 7) En la reivindicación 6ª -numerada como 1.5-, folio 9, aparecen los términos *luz*, *luces* que tienen dos (¿o más?) interpretaciones que podrían aplicarse a la solicitud, por lo que se le sugiere al solicitante sustituirlos por otras expresiones más concretas, principalmente si se tiene en cuenta que en la descripción no se aclara el significado aplicable a cada caso.

Las reivindicaciones no cumplen con los requisitos de claridad, de concisión y de sustento por la descripción que exige el Art. 30 de la Decisión 486.

Se deben presentar, entonces, nuevos capítulos descriptivo y reivindicatorio, ambos completos, junto con un nuevo juego de dibujos, donde se hayan corregido todas las objeciones que se han hecho arriba. Esto con el fin de evitar -cuando solo se presentan algunas páginas sueltas corregidas- que el lector tenga que desplazarse desde un sitio a otro de la solicitud y luego regresar a donde estaba antes sin perder la ilación de la lectura, porque esto produce confusión y afecta negativamente la claridad de dichos capítulos.

4. De las excepciones a la patentabilidad Las reivindicaciones 9ª a 17ª -numeradas 2 a 2.8- reclaman un procedimiento para la implantación de un dispositivo definido antes. Este procedimiento: por una parte, es un método terapéutico (artículo 20 D486 letra d)), y, por otra parte, no tiene carácter industrial (no pertenece a la propiedad industrial), porque el procedimiento en cuestión sólo se puede aplicar, en cada ocasión en sea necesario, **una vez en un paciente**.

5. De la determinación del estado de la técnica

- La fecha que se ha tenido en cuenta para determinar el Estado de la Técnica es la

Fecha de presentación de la solicitud nacional: 03-11-07.

Durante la búsqueda de anterioridades se encontraron los siguientes documentos, que forman parte del estado de la técnica más cercano al objeto de la solicitud:

n.º	Documento	Título	Fecha de publicación
D1	Patente US 5 261 878, cuyo inventor es Álvaro Galindo, quien le cedió sus derechos a The Regents of the University of California	«Double balloon pediatric ductus arteriosus stent catheter and method of using the same» (Un catéter pediátrico con doble globo, provisto de un conducto que se inserta dentro del ductus arteriosus, y un método para emplearlo)	93-11-16
D2	Patente US 5 702 421, cuyo inventor es Bernhard Schneidt	«Closure device for closing a vascular opening, such as patent ductus arteriosus» (Un dispositivo de cierre para ocluir una abertura vascular, tal como el ductus arteriosus evidente)	97-12-30

Se anexan copias de las páginas pertinentes

NOTAS: No se realizó una evaluación de los demás requisitos de patentabilidad, porque se objetó la claridad, la definición, la concisión y el sustento de las reivindicaciones. Una vez hayan sido superadas las objeciones establecidas en este Concepto Técnico, se podrán hacer los exámenes correspondientes.

No obstante lo anterior, con base en los documentos detectados hasta ahora, no se prevén objeciones respecto a la novedad de lo divulgado en la solicitud.

6. De las conclusiones:

Los requisitos de patentabilidad de la presente solicitud se encontrarían afectados negativamente por la falta de claridad del título, de la descripción y de las reivindicaciones y por la falta de concisión, definición y sustento de estas últimas.

En cumplimiento del artículo 85 en concordancia con el artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se le indica al solicitante que debe dar respuesta dentro del término de treinta días contados a partir de la fecha de notificación de la presente comunicación. En caso de no dar respuesta al presente requerimiento, o si a pesar de la respuesta subsistieran los impedimentos para la concesión, se denegará la patente.

Notifíquese el presente oficio conforme a lo dispuesto en el artículo 8 de la resolución reglamentaria n.º 00210 del 15 de enero de 2001, advirtiéndole que contra él no procede recurso alguno en la vía gubernativa.



ALIX CARMENZA CÉSPEDES DE VERGEL
Jefe de División de Nuevas Creaciones

El anterior requerimiento fue notificado por fijación en lista, de fecha
26 JUN. 2008

CONCEPTO TÉCNICO n.º 1698	EXAMINADOR TÉCNICO Código n.º 202009
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US005261878A

United States Patent [19]
Galindo

[11] **Patent Number:** **5,261,878**
 [45] **Date of Patent:** **Nov. 16, 1993**

- [54] **DOUBLE BALLOON PEDIATRIC DUCTUS ARTERIOSUS STENT CATHETER AND METHOD OF USING THE SAME**
- [75] **Inventor:** Alvaro Galindo, Tarzana, Calif.
- [73] **Assignee:** The Regents of the University of California, Oakland, Calif.
- [21] **Appl. No.:** 885,946
- [22] **Filed:** May 19, 1992
- [51] **Int. Cl.⁵** A61M 29/00
- [52] **U.S. Cl.** 604/96; 606/194
- [58] **Field of Search** 604/96-101, 604/53, 54, 55; 606/194

[56] **References Cited**

U.S. PATENT DOCUMENTS

4,456,011	6/1984	Warnecke	604/101
4,741,328	5/1988	Gabbay	604/99
4,771,765	9/1988	Choy et al.	604/101 X
4,794,928	1/1989	Kletschka	604/101 X
4,976,692	12/1990	Atad	604/101

OTHER PUBLICATIONS

Transluminally-Placed Endarterial Crafts—Dotter—Investigative Radiology Sep.-Oct. 1967 vol. 4, pp. 329-332.
 Intravascular Stents and Transluminal Angioplasty—Sigwart et al.—New England Journal of Medicine, Mar. 19, 1987, pp. 701-706.
 Expandable Intraluminal Graft: A Preliminary Study—Palmaz et al.—Radiology Jul. 1985, pp. 73-77.
 Atherosclerotic Rabbit Aortas: Expandable Intraluminal Grafting—Palmaz et al.—Radiology 1986; 160:723-726.
 Expandable Intraluminal Vascular Graft: A Feasibility Study—Palmaz et al.—Surgery Feb. 1986, pp. 199-205.
 Expandable Intrahepatic Portacaval Shunt Stents:

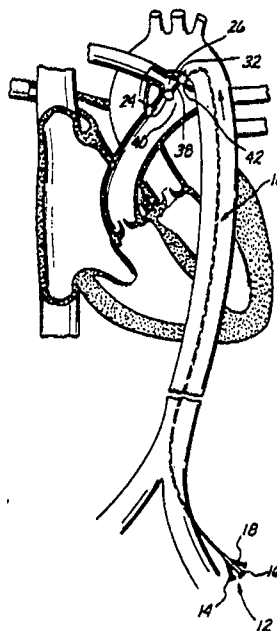
Early Experience in the Dog—Palmaz et al.—AJR 145:821-825, Oct. 1985.
 Balloon-Expandable Intravascular Stent—Palmaz et al.—AJR 150:1263-1269, Jun. 1988.
 Use of Endovascular Stents in Congenital Heart Disease—O’Laughlin et al.—Circulation 1991;83:1923-1939.
 A Novel Method to Maintain Ductus Arteriosus Patency—Coe et al.—J Am Coll Cardiol 1991;18:837-841.
 Use of Intravascular Endoprosthesis . . . —Moore et al.—JACC vol. 17, No. 2, Feb. 1991:19A.
 Redilating Ductal Stents in Newborn Lambs—Coe et al.—Abstracts From the 64 Scientific Sessions, II-545.
 Introduction to Intravascular Stents—Richard A. Schatz—Cardiology Clinics—vol. 6, No. 3, Aug. 1988.

Primary Examiner—John D. Yasko
Attorney, Agent, or Firm—Daniel L. Dawes

[57] **ABSTRACT**

A cardiac catheter for use in maintaining the patency of the ductus arteriosus in infants is provided with two inflatable balloons, a distal end balloon and a stent balloon. Each balloon is independently inflatable. The stent is carried temporarily on the stent balloon and is delivered by the catheter to the site of the ductus arteriosus. Expansion of the stent balloon expands the stent and places it at the target site. The stent balloon is confidently and reliably placed in the ductus arteriosus by first inflating the distal end balloon and withdrawing the catheter until abuts the opening of the ductus arteriosus through which it has been previously disposed. When this abutment is realized, the stent balloon is necessarily positioned appropriately within the ductus arteriosus. While maintaining the inflation of the distal end balloon, the stent balloon is inflated and the stent placed. After placement, both the distal end balloon and stent balloon are deflated and the catheter withdrawn.

20 Claims, 2 Drawing Sheets



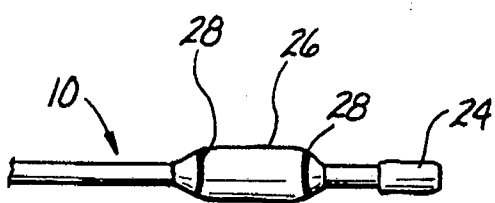


Fig. 2

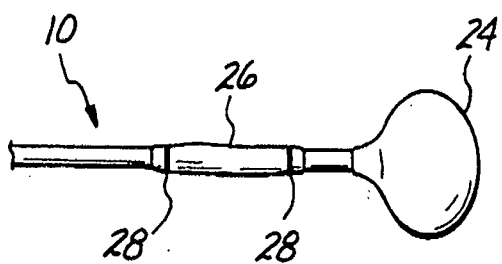


Fig. 3

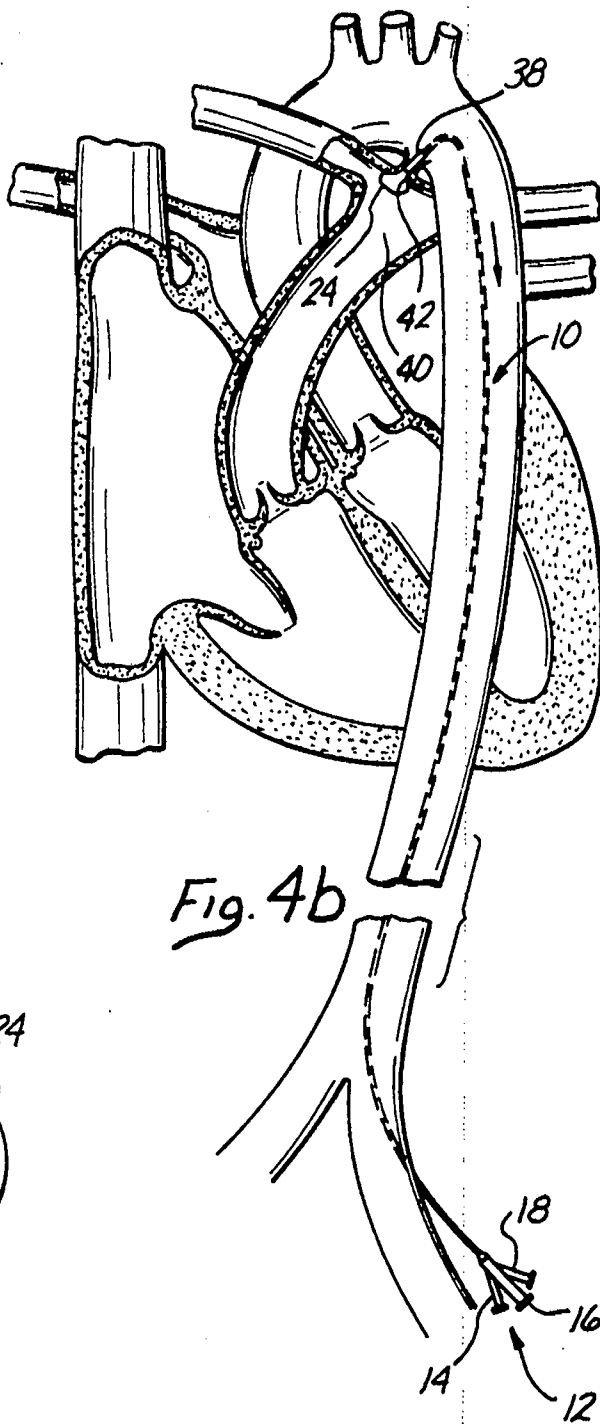


Fig. 4b

DOUBLE BALLOON PEDIATRIC DUCTUS ARTERIOSUS STENT CATHETER AND METHOD OF USING THE SAME

BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention relates to the field of cardiac catheters and in particular to catheters used to place stents in infants and the methods by which such catheters may be used for pediatric stent placement.

2. Description of the Prior Art

Work began as early as 1969 using nonexpandable stainless steel coils in combination with angioplasty catheter techniques for the placement of stents in dog femoral arteries C. T. Dotter, "Transluminally placed coil spring endarterial tube grafts: Long term patency in canine popliteal artery," Invest. Radiol 4:329-331 (1969). Following Dotter, several different types of stent designs were devised, but each of these designs suffer from limitations which prevented their success in clinical application. These limitations included bulky configurations that made delivery to target lesions difficult, unpredictable expansion of the device, migration due to stent-vessel mismatch, abrupt thrombosis, or gradual restenosis from intimal hyperplasia.

Evolving from these early efforts are three basic designs which include a spring-loaded stent, usually made of stainless steel and constrained to a small diameter on a delivery catheter. The stent is allowed to spring open to a predetermined diameter when the constraint is removed. See Sigwart et al. "Intravascular stents to prevent occlusion and restenosis after transluminal angioplasty," N. Engl. J. Med. 316:701-706 (1987).

A second type of stent relies upon thermal expansion. Stents made of nitinol are initially configured as small diameter wires or coils and expand to predetermined shapes with the application of body heat.

A third type of stent is introduced with a balloon catheter. Stents of this type rely on plastic deformation of the metal caused by mechanical expansion when driven by a balloon. Woven stainless steel wire stents are crimped over conventional balloon catheters and then expanded after being positioned at the target site. When the balloon is inflated, the stent is embedded in the vessel wall. Following balloon deflation and removal, the stent remains in place, holding the vessel open if properly placed initially, Palmaz et al., "Expandable intraluminal graft: Preliminary study" Radiology 156:73-77 (1985); Palmaz et al. "Expandable intraluminal grafting," Radiology 160:723-726 (1986); Palmaz et al. "Expandable intraluminal vascular graft: A feasibility study," Surgery 99:199-205 (1986); Palmaz et al. "Expandable intrahepatic portacaval shunt stents: Early experience in the dog," AJR 145:821-825 (1985). See also generally, Schatz, "Introduction to intravascular stents," Interventional Cardiology Clinics Vol. 6 No. 3 pp 357-372 (1988); Palmaz, "Balloon-expandable intravascular stent," AJR 150:1263-1269 (1988); O'Laughlin, "Use of Endovascular Stents in Congenital Heart Disease," Circulation Vol. 83, 1923-39 (1991). However, each of these prior art catheters for delivering stents did so by means of a single balloon angioplasty catheter.

In a variety of congenital pediatric heart defects, there is a need for augmented pulmonary blood flow due to pulmonary atresia or stenosis. These defects include Tetralogy of Fallot, tricuspid atresia and complex forms of pulmonic stenosis. It is advantageous in

these applications to maintain a patent ductus arteriosus. In other words, when blood circulation through an infant's heart is blocked or substantially restricted, blood flow from the heart to the lungs is diverted through the ductus arteriosus which is open in the infant's heart only for a relatively short period of time after birth. As the ductus arteriosus closes, as a result of normal heart development, no alternative path then remains to allow for adequate pulmonary circulation in the defective heart. In the worst cases, the infant will eventually become cyanotic and suffocate.

Conventional treatment includes drug treatments by infusions of prostaglandin which inhibits the closing of the ductus arteriosus. This treatment has a disadvantage that the infant must be kept on constant intravenous infusions of the drug until it has become large enough to survive cardiac surgery.

Ultimately, a pulmonary shunt, either through an artificial prosthetic, diversion by a Blalock-Taussig shunt, or central shunt must be performed. These latter procedures involve surgical intervention with inherent anesthesia and perioperative risks.

Therefore, it is desirable to evaluate perfected cardiac catheterization techniques to establish a systematic pulmonary artery communication. What has been attempted in the prior art is the placement of stents in the ductal arteriosus using conventional angioplasty catheters. See Coe, "Redilating Ductal Stents in Newborn Lambs," 2163 Abstracts from 64th Scientific Sessions II-545; Moore et al., "Use of an Intravascular Endoprosthesis (stent) to Establish and Maintain Short Term Patency of the Ductus Arteriosus in Newborn Lambs," JACC Vol. 17 No. 2 (1991); and Coe et al., "A Novel Method to Maintain Ductal Patency," JACC Vol. 17 No. 2 (1991).

In Coe's study in newborn lambs, catheters were introduced via a cutdown in the neck under general anesthesia. A stainless steel stent which was securely mounted on a coronary angioplasty catheter, was introduced into the external jugular vein and manipulated through the right heart under fluoroscopy to place the balloon carefully in the ductus arteriosus. The position of the ductus was previously determined angiographically. The balloon on the catheter was inflated to release the stent in the ductus arteriosus without embolization.

The difficulty with this technique, however, is proper placement in the ductus arteriosus which is a very small and short tubular shunt in the infant's cardiac circulation system near the heart. The stent, although made of stainless steel, is very thin and can be seen only with difficulty under fluoroscopy, which is the only means for determining when and if the stent is properly placed. Improper placement within the ductus arteriosus could result either in failure of the stent to maintain the ductus arteriosus open and/or possible creation of clotting site with resulting complications from embolism.

The inclusion of radiographic markers, either on the stent or the delivery catheter, helps determination of the location of the stent, but provides no assistance in determining whether or not the stent is properly placed with ductus.

Therefore, what is needed is an apparatus and method which can be used in combination with conventional fluoroscopy to allow accurate and secure placement of a stent in the ductus arteriosus of an infant.



United States Patent [19]
Schneidt

[11] **Patent Number:** **5,702,421**
[45] **Date of Patent:** **Dec. 30, 1997**

[54] **CLOSURE DEVICE FOR CLOSING A VASCULAR OPENING, SUCH AS PATENT DUCTUS ARTERIOSUS**

[76] **Inventor:** **Bernhard Schneidt, Johanniter Strasse 14, 63571 Gelnhausen, Germany**

[21] **Appl. No.:** **585,114**
[22] **Filed:** **Jan. 11, 1996**

[30] **Foreign Application Priority Data**
Jan. 11, 1995 [DE] Germany 295 00 381.2 U
Aug. 24, 1995 [EP] European Pat. Off. 95113341.2

[51] **Int. CL⁶** **A61B 17/08**
[52] **U.S. Cl.** **606/213; 600/32; 604/285; 606/215**

[58] **Field of Search** **606/213, 215, 606/151; 600/32; 623/11; 604/285, 286**

[56] **References Cited**
U.S. PATENT DOCUMENTS
3,874,338 4/1975 King et al. .
4,007,743 2/1977 Blake .
5,108,420 4/1992 Marks .
5,334,137 8/1994 Freeman .
5,334,217 8/1994 Das 606/213
5,382,260 1/1995 Dormandy, Jr. et al. .
5,397,331 3/1995 Himpens et al. 606/151

FOREIGN PATENT DOCUMENTS

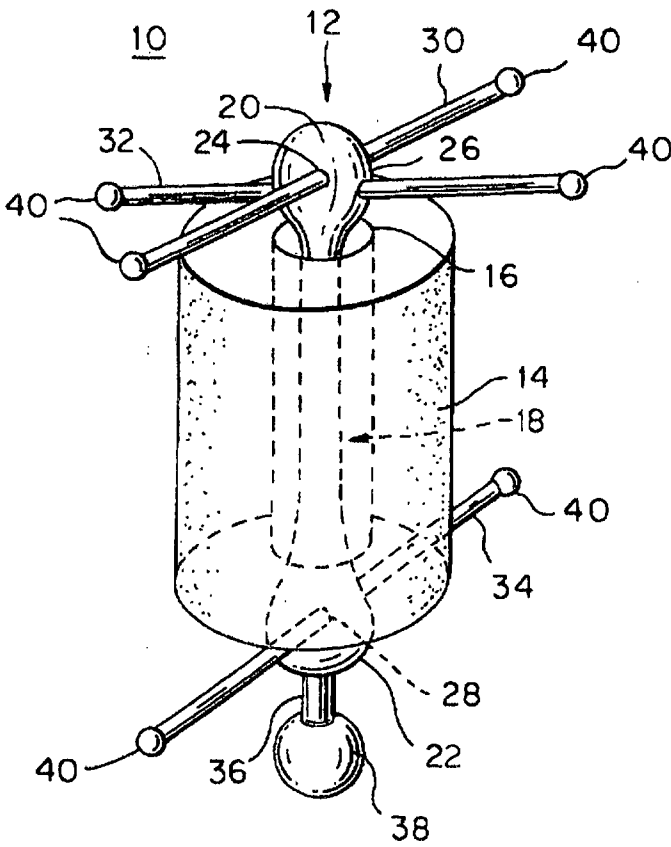
362113	4/1990	European Pat. Off. .
541063	5/1993	European Pat. Off. .
233303	2/1986	German Dem. Rep. .
4222291	1/1994	Germany .
5724132	1/1979	Japan .
9316650	9/1993	WIPO .
9409705	5/1994	WIPO .

Primary Examiner—Michael Buiz
Assistant Examiner—Tina T. D. Pham
Attorney, Agent, or Firm—Dennison, Meserole, Pollack & Scheiner

[57] **ABSTRACT**

The invention relates to a closure device (10) for closing an anatomical anomaly in the form of a vascular opening (80), such as patent ductus arteriosus, atrial septal defect, foramen ovale or ventricular septal defect, including a closure body (14) that extends at least within the vascular opening and wirelike, elastic locking members (30, 32, 34). In order to improve a fixation of the closure device and to preclude injuries, it is proposed that the locking members (30, 32, 34), on their free ends, be embodied spherically or in lentiform fashion or be provided with spherical or lentiform elements (40).

12 Claims, 6 Drawing Sheets



CLOSURE DEVICE FOR CLOSING A VASCULAR OPENING, SUCH AS PATENT DUCTUS ARTERIOSUS

BACKGROUND

The invention relates to a closure device for closing an anatomical anomaly in the form of a vascular opening, such as patent ductus arteriosus (PDA), atrial septal defect, foramen ovale or ventricular septal defect, including a closure body that extends at least within the vascular opening and wirelike, elastic locking means extending outside the vascular opening, which are embodied as spherical or lentiform on their free ends or are provided with spherical or lentiform elements and are preferably polished laser welded beads or polished titanium balls. The invention also relates to a closure device for closing an anatomical anomaly in the form of a vascular opening, such as patent ductus arteriosus, atrial septal defect, foramen ovale or ventricular septal defect, including a closure body with an axially extending middle part.

The human blood circulation comprises a coronary circuit and a pulmonary circuit. In the embryonic phase of human development, the two circuits are joined to one another by the ductus arteriosus. The ductus connects the aorta (circulation to the body) to the pulmonary artery (pulmonary circuit). In normal development of an infant, this ductus grows shut after birth. If development is defective, it can happen that the ductus does not grow shut, and as a result the two blood circuits are still joined even after birth. This can severely shorten the infant's life expectancy.

It is known to close the PDA by surgical intervention. However, this intervention is extremely expensive and involves risk to the patient.

It is also known for the patent ductus arteriosus to be closed by means of an IVALON® foam plug (Porstmann's technique). A guide splint is fed through a femoral artery into the aorta through the ductus into the pulmonary artery, and from there through the right ventricle and the right atrium of the heart and finally through the opposite femoral veins back to the outside. Next, the ductus plug is thrust into the ductus, where it is "wedged firm". Because of the great difference in pressure between the aorta and the pulmonary artery, stringent demands are made of the locking of the ductus plug inside the ductus.

Relatively large plugs must therefore be used, which are compressed in length by a factor of 10 and are 30% larger than the diameter of the ductus. Correspondingly large gateways are needed to thread the plug into the femoral artery. In infants, the lumen of the vessel is too small, and in children weighing less than 30 kg it is often too small for such an intervention to be made.

The closure device of the type referred to at the outset can be found in East German Patent Disclosure DD 233 303 A1. In the known closure device, the closure body has a single-shell hyperboloid-like outline and may comprise metal, a metal alloy, plastic and similar materials. Extending outside the closure body are wirelike locking means that terminate in a point, so the danger exists that vessel walls will be injured.

For implanting the closure device, the closure device is grasped by a holding wire extending inside a securing tube and is thrust through a catheter. Because of the shape of the closure body and the fact that the ends of the locking means terminate in a point, there is not only considerable danger of injury to a patient but also the possibility of retracting a mispositioned closure device back into the catheter.

SUMMARY OF THE INVENTION

The object of the present invention is to improve a closure device of the type referred to at the outset in such a way that locking of the closure device inside the vascular opening is improved, thus making a secure closure available. In addition, the implantation should be facilitated, with the possibility of correcting misplacements without difficulties.

According to the invention, this object is substantially attained in that the locking means are positionally fixed with the closure body on the face end by suturing or extend entirely or nearly entirely within the closure body. By the embodiment according to the invention of the closure device, it is assured that injury to the vessel walls by the locking means is precluded. As a result, there is the advantage that upon implantation of the closure device, a change in position of the closure is easily possible. The spherical or lentiform ends of the locking means also assure that when there is a major pressure difference in the vessels joined by the ductus, the fixing elements that normally contact the inner walls of the vessels cannot cause injury from motion of the closure device. The spherical ends also prevent injury even if the device might be transported through the vessels without being secured by the catheter. The locking elements, which can also be called fixing elements, preferably extend in raylike fashion from the closure body. Alternatively, it is possible to embody the locking means as loops, which present larger contact surfaces for the locking means along the inner walls of the vessel. The locking elements, which perform the function of spring elements, may comprise platinum, titanium, or other suitable materials. It is also possible to use a titanium-nickel alloy with a platinum or titanium coating. The spherical or lentiform, i.e., oval, ends may be polished titanium balls or laser welded beads.

The locking means themselves are positionally fixed with the closure body on the face end by suturing. Alternatively, the locking means can extend entirely or nearly entirely within the closure body and be foamed into it. This provision assures that the closure body, if it is a plastic part, cannot be displaced or compressed as a result of the pressure difference at the ends of the vascular opening.

The locking means may be joined together via a middle part extending axially inside the closure body. By means of the middle part, a connection can then be made with the locking means associated with the various vessels. The middle part itself may be embodied in one piece or in multiple parts, for instance in telescoping fashion. Receptacles for the locking means can be embodied as holes made in the end portions of the middle parts. The end portions of the middle part may be embodied as separate receptacles which are joined, for instance by welding, to the middle part.

According to the invention, each PDA should be closed as tightly as possible and with as much implant composition as possible. This also assures that the space in the guide catheter will always be optimally filled; that is, the implant material (IVALON®) or similar suitable material can be displaced to the applicator tongs with only a single expenditure of force. To preclude loosening or uncontrolled shifting of the implant relative to the locking elements, it is provided according to the invention that these elements are always sutured to the implant. To achieve optimal filling of the ductus, the device may be embodied either with a middle part or without a middle part.

In a further feature of the invention, a locking means, beginning at this middle region, and/or the middle part of the axial length of the closure body may have a formed-on feature such as a coupling, which can be grasped by guide