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PATENT DECLARATION FORM (CONVENTION) COMMONWEALTH OF AUSTRALIA

Patents Act 1952

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DECLARATION IN SUPPORT OF A CONVENTION APPLICATION FOR A PATENT

To be signed by the applicant(s) or in the case of a body corporate to be signed by a person authorised by the body corporate.

	biglies of a partier defined by the body corporate.
	In support of the Convention application made for a patent for an invention entitled
(e) Insert title	(a) Prosthesis for preventing the gastric reflux in the
of invention.	oesophagus
(b) Insert full name(s) of	I/We(b) Norman Godin
declarant(s),	
(c) Insert address(es) of	of (c) 4, Quai du Seujet, CH-1201 Geneve
declarent(s).	Switzerland
	do solemnly and sincerely declare as follows:—
	1. I am/We are the applicant(s) for the patent
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	d. I am/We are authorised by
	2. The basic application(s) as defined by Section 141 of the Act was/were made in the following country or countries on the following date(s) namely:—
(d) Insert country in	in (d) Switzerland on (e) 20 July 1989
which basic application(s)	by(f) Norman Godin
was/ware filed.	in (d) on (e)
(e) Insert date	_{by} (f)
of basic application(s).	in (d) on (e)
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арриссиния	3. I am/We are the actual inventor(s) of the invention referred to in the basic application.
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(g) Insert full name(s) of	9 (6)
actual inventor(s) (h) insert	of (h)
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	is/are the actual inventor(s) of the invention and the facts upon which the applicant(s) is/are entitled to
	make the application are as follows:
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derive(s) title from actual	
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the invention from the actual	4. The basic application(s) referred to in paragraph 2 of this Declaration was/were the first
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CHIVENNION	

DECLARATION

I, Pierre-Antoine CHOPARD

of 19 chemin Champs-de-Vaux, 1246 Corsier (Switzerland),

hereby certify that to the best of my knowledge and belief the following is a true translation into the English language of Swiss Patent Application No. 02 703/89-2, which has been made by me and for which I accept responsibility.

signed this 15^{M} day of Way , 1991.

Preue Dutoni Chaprun

Pierre-Antoine CHOPARD

(12) PATENT ABRIDGMENT (11) Document No. AU-B-59364/90 (19) AUSTRALIAN PATENT OFFICE (10) Acceptance No. 629664

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 PROSTHESIS FOR PREVENTING THE GASTRIC REFLUX IN THE OESOPHAGUS
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 NORMAN GODIN
- (72) Inventor(s)
 NORMAN GODIN
- (74) Attorney or Agent
 DAVIES COLLISON CAVE, GPO Box 3876, SYDNEY NSW 2001
- (56) Prior Art Documents
 US 4846836
- (57) Claim
- 1. A prosthesis for preventing gastric reflux in the eosophagus comprising:
- a fixing portion having a circular cross section substantially corresponding to the cross-section of the eosophagus, for fixing the prosthesis to the wall of the eosophagus; and
- a valve means to control the flow of material in the eosophagus comprising a resilient tubular shaped wall,

said valve means depending at one end from the fixing portion, the tubular wall progressively collapsing toward the opposite end to substantially resiliently close the flow cross-section of the valve means;

said opposite end being intended to be placed in the eosophagus downstream of the fixing portion so that, in use, any force generated on an alimentary bolus by the peristaltic wave of the eosophagus tends to space the resiliently collapsed wall apart, while

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any force in the opposite direction tends to prevent gastric reflux through the collapsed end wall as long as it does not exceed a limit substantially greater than that generated by the peristaltic wave of the of the eosophagus and thus causing an at least partial inversion of said tubular shaped valve means.

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(74) Mandataires: DOUSSE, Blasco etc.; 7, route de Drize,

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(54) Title: PROSTHESIS FOR PREVENTING THE GASTRIC REFLUX IN THE OESOPHAGUS

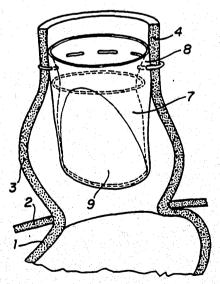
(54) Titre: PROTHESE POUR EMPECHER LES REFLUX GASTRIQUES DANS L'ŒSOPHAGE

(57) Abstract

The prosthesis is configured like an anti-return valve arranged preferably in the area where the oesophagus and the hiatal hernia meet. Said valve is comprised of a tubular part (7) associated with an annular fixing element (8). The tubular part flatens progressively to form two joined lips (9, 10). It is possible to form said valve with a wall thickness which increases from the free end of the lips (9 and 10) towards the annular fixing part (8) in order to avoid an easy returning under the effect of the surging pressure. During the passage of the alimentary bolus, the lips (9, 10) are spaced apart and joined again owing to their natural elasticity. A metal wire (16) embedded in the annular fixing part (8) is used for the radiologic marking.

(57) Abrégé

Cette prothèse a la forme d'une valve anti-retour disposée de préférence dans la zone où l'œsophage et l'hernie hiatale se rejoignent. Cette valve comporte une partie tubulaire (7) associée à un élément annulaire de fixation (8). La partie tubulaire s'aplatit ensuite progressivement pour former deux lèvres jointives (9, 10). Il est possible de former cette valve avec une épaisseur de paroi qui augmente de l'extrémité libre des lèvres (9 et 10) en direction de la partie annulaire de fixation (8) pour éviter le retournement trop facile sous l'effet de la pression de reflux. Lors du passage du bol alimentaire, les lèvres (9, 10) s'écartent puis se rejoignent grâce à leur élasticité naturelle. Un fil métallique (16) noyé dans la partie annulaire de la fixation (8) sert au repérage radiologique.



PROSTHESIS FOR PREVENTING THE GASTROC REFLUX IN THE OESOPHAGUS

The present invention relates to a prosthesis for preventing gastric reflux in the esophagus, including a valve associated with an annular fixation portion and having an opening that is elastically kept closed.

Esophagitis is caused by chronic gastric reflux. Although the mucus of the stomach is capable of withstanding the highly acid pH of the gastric secretions, which is close to 1, this is not the case for the mucus of the esophagus. Consequently, when this reflux is chronic, it attacks the mucus of the esophagus and creates ulcers, which over the long term can cause shrinkage of the esophageal conduit.

This gastric reflux is generally associated with a hiatal hernia. The most currently used therapy for this type of affliction makes use of medicines. There are three categories: antacids, which tend to make the environment neutral by the intake of an alkaline product, H2 antihistamines, which fix on the H2 receptor of the parietal cell. Recently, a new medicine has been proposed that in turn blocks the production of H+ ions by the parietal cell. However, this medicine has no further effect as soon as it ceases to be administered, and it cannot be taken continuously, because it might cause tumors, which has been confirmed at least for the rat. Finally, the third class comprises medicines that increase the motility of the esophagus and the stomach and tend to reduce the length of contact of the acid reflux with the esophagus. This therapy does not attack the primary cause of the ailment, which is gastric reflux, which reappears as soon as the treatment with medicine stops, so that the patient is forced to take medication permanently. This solution is clearly unsatisfactory both medically and economically.

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As an alternative to this medication route, it has already been proposed to use an external prosthesis for mechanical opposition to gastric reflux. This external prosthesis is formed by an elastically extensible ring disposed around the end where the esophagus discharges into the stomach. By thus surrounding the base of the esophagus, the centripetal force that this ring exerts offers a flow resistance that tends to prevent gastric reflux from rising in the esophagus. Nevertheless, the effect of this ring is equally manifest with gastric reflux and with deglutition of the gastric contents. Consequently, the centripetal pressure cannot be selected to be too high, or else it may cause an unacceptable impairment to swallowing. The absence of selectivity in this solution in terms of the direction of flow does not make it possible to guarantee total efficacy of this external prosthesis. It has also been found that the external prosthesis can be pushed upward by the pressure of gastric reflux, so that the base of the esophagus is again exposed to attack by the acidity of the gastric juices. This ring is located outside the esophagus, and so its position cannot be further modified by endoscopy. Shifts of this external prosthesis in the abdominal cavity limit its use and can have risks.

These disadvantages explain why the use of this prosthesis is not widespread, because it does not offer a sufficient guarantee. If it fails, then recourse to medication must be made anew, and the proportion of failures has proved to be high.

Finally, there are also surgical procedures, in particular the Nissen-Rossetti fundoplicature, which comprises making a sleeve with the gastric fundus surrounding the heart, under the diaphragm. The disadvantage of such an operation is that in the case of deficient esophageal peristalsis it may cause severe dysphagia. Still other surgical procedures exist. Nevertheless, all the surgical solutions have postoperative risks, such as a

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recurrence of reflux after relaxation of the sutures, dysphagia when the sleeve is too tight, and sliding of part of the stomach upstream of the sleeve, thus causing severe reflux eosophagitis. This patient thus operated upon can also neither burp nor vomit, which is difficult for some patients to tolerate.

A prosthesis of an eleastomer material has also already been proposed in US Patent 4,846,836, and is intended to be placed in the eosophagus and includes a cone inside a tubular portion intended for fixation of the prosthesis. The cone has a slit apex and is aimed toward the stomach, comprising a sort of funnel that ends in a valve, the slit of which is intended to open by a peristaltic thrust exerted on the alimentary bolus, but to prevent flow in the opposite direction. A second slit, made between the base of the cone and the tubular portion, is intended to open under a certain reflux pressure to enable vomiting.

A major disadvantage of this prosthesis is due to the fact that the gastric juices must pass through a substantially reduced cross section of the valve at the apex of the cone; this cone is necessary to enable flow in reverse to have access to the second opening intended for reflux in the case of vomiting. It is clear that such a valve comprises a certain hindrance to the patient, who will have difficulty in swallowing, particularly solids, because of the shrinkage at the passage through the slit, which can cause pain that is difficult to tolerate.

The object of the present invention is at least in part to overcome the disadvantages of the above arrangements.

To this end, the subject of this invention is a prosthesis for preventing gastric reflux in the eosophagus comprising:

a fixing portion having a circular cross section substantially corresponding to the cross-section of the eosophagus, for fixing the prosthesis to the wall of the eosophagus; and

a valve means to control the flow of material in the eosophagus comprising a resilient tubular shaped wall,

 said valve means depending at one end from the fixing portion, the tubular wall progressively collapsing toward the opposite end to substantially resiliently close the flow cross-section of the valve means;

said opposite end being intended to be placed in the eosophagus downstream of the fixing portion so that, in use, any force generated on an alimentary bolus by the peristaltic wave of the eosophagus tends to space the resiliently collapsed wall apart, while

any force in the opposite direction tends to prevent gastric reflux through the collapsed end wall as long as it does not exceed a limit substantially greater than that generated by the peristaltic wave of the of the eosophagus and thus causing an at least partial inversion of said tubular shaped valve means.

The essential advantage of the proposed arrangement is due to the fact that the same valve, while it has a unidirectional effect, enables reflux when the pressure is sufficient, that is,

in the case of vomiting. This valve also has the enormous advantage that in the open position it offers a passage cross section that is substantially equal to that of the esophagus, thus permitting easy swallowing of food.

The accompanying drawing schematically and by way of example illustrates an embodiment and two variants of the prosthesis that is the subject of the present invention.

Fig. 1 is a perspective view in section of one embodiment of this prosthesis, affixed to the base of the esophagus.

Fig. 2 is an elevational view of the embodiment of Fig. 1.

Fig. 3 is a sectional view along the line III-III of Fig.

2.

7.

Fig. 4 is an elevational view of a variant of Figs. 1-3.

Fig. 5 is a sectional view along the line V-V of Fig. 4.

Fig. 6 is a sectional view along the line VI-VI of Fig. 5.

Fig. 7 is a view similar to Fig. 4, of a variant.

Fig. 8 is a sectional view along the line VIII-VIII of Fig.

Fig. 9 is a view along the line IX-IX of Fig. 7.

Fig. 10 is a perspective view of the variant of Figs. 7-9, disposed in a hiatal hernia.

Fig. 1 shows the top of the stomach 1, which has a hiatal hernia 3 of the diaphragm 2. Although gastric reflux is not always linked with the presence of such a hernia, nevertheless it is the most frequent cause of this affliction. The base of the esophagus 4 opens into this hiatal hernia 3.

The embodiment shown in Figs. 1-3 has a valve formed of a tubular portion 7 associated with an annular fixation element 8. This tubular portion, which moreover may itself form the fixation element, then flattens progressively to form two joined lips 9 and 10. This solution offers very slight resistance to the passage of the gastric juices and requires little or no capacity for

extension, in so far as it suffices that the lips 9 and 10 are spaced apart from one another to allow passage to the flow. This prosthesis can be made from a silicone-based elastomer with two components of medical quality, sold under the mark Silastsic® by Dow Corning Corporation, or it may be made of a biocompatible polymer such as that described in US Patent 4,657,544 or in US Patent 4,759,757, which can be suitable for such an application.

This is a solvent-free graft polymer with two hydrophilic or hydrophobic components, into which an inorganic water-soluble salt that has been ground and sifted is incorporated. A tube is then formed, and the salt crystals are washed out of the tube thus formed to make a honeycombed structure that increases flexibility and makes it possible to improve the adhesive bonding properties, in the case where this mode of fixation is used. Aside from the aforementioned elastomers, fluoroelastomer compounds such as Viton® can be cited, along with rubbers of the butyl type. valves can be formed with a wall thickness that increases from the free end of the lips 9 and 10 toward the annular fixation part 8, to avoid overly easy inversion under the influence of the reflux pressure. It can be noted that this embodiment affords a large surface area on which the reflux pressure can act to close the lips 9 and 10. If the tubular portion is slightly more rigid because of its increased thickness, the valve functions essentially by moving the lips 9 and 10 farther apart and closing them again.

As can also be observed in Figs. 1-3, a very fine metal wire 16 can be embedded in the annular fixation element, with a view to permitting radiologic marking of the position of the valve.

Other embodiments based on this same concept are conceivable. The variant shown in Figs. 4 and 5 is distinguished essentially by the fact that the flattening of the annular portion

11 to form the lips 12 and 13 is much more sudden, thus reducing the axial dimension of the valve. This dimensional reduction has the advantage of occupying less space and making it possible to accommodate the prosthesis in its entirety in practically all hiatal hernias. In this example, the axial dimension of the prosthesis is on the order to 15 to 20 mm. However, the primary difference in this variant is the fact that in the position of repose, the two lips 12 and 13 remain separated as shown in Fig. 5, so as to facilitate the passage of the gastric juices and prevent food residues and saliva from remaining in the valve. keeping the lips 12 and 13 apart, this risk is practically avoided, and saliva can flow into the stomach without the aid of any force for spacing the lips 12 and 13 apart. In this variant, the thickness of the wall of the level of the end of the lips 12 and 13 is on the order of 0.2 to 0.4 mm, while it thickens to attain a value of 1.2 to 1.7 mm in the annular portion 11.

In the case of gastric acid reflux, the pressure exerted on the outer faces of the flattened portions that form the lips 12 and 13 cause the closure of these lips. Even if a small quantity of gastric acid passes between the lips, this reflux does not threaten to exceed the level of the valve and hence to attack the esophogeal mucus. As soon as the reflux pressure disappears, the lips 12 and 13 move apart again to the position of repose shown in Fig. 5 and allow the acid that may be located in the valve to drop downward again.

If the reflux pressure increases substantially, which occurs only in the case of vomiting, the lips 12 and 13 invert and allow the flow to pass in the opposite direction. In the variant shown in Figs. 4 and 5, it has been found that in the case of inversion, these lips return to their initial position by their intrinsic elasticity.



The second variant shown in Figs. 7-10 differs from that of Figs. 4 and 5 in that the lips 14 and 15 are asymmetrical, forming a D-shaped opening between them instead of the elongated O formed by the opening between the symmetrical lips 12 and 13. The reason for the choice of this asymmetrical form of the opening made between the lips 14 and 15 is the fact that the stomach itself has an asymmetrical shape, as illustrated in Fig. 6, such that the reflux pressure that is exerted on the lips 14 and 15 is not vertical but rather lateral, and that the lip 14 is thus subjected to higher pressure than the lip 15. Providing the lip 15 with a convex shape thus further facilitates the passage of the gastric juices. Contrarily, the straight lip 14 offers less resistance to deformation, and since it is subjected to the greatest reflux pressure, which comes from the right, it is pressed against the lip 15 and closes the orifice of the passage in case of reflux, with the lip 15 remaining practically immobile.



The claims defining the invention are as follows:

1. A prosthesis for preventing gastric reflux in the eosophagus comprising:

a fixing portion having a circular cross section substantially corresponding to the cross-section of the eosophagus, for fixing the prosthesis to the wall of the eosophagus; and

a valve means to control the flow of material in the eosophagus comprising a resilient tubular shaped wall,

said valve means depending at one end from the fixing portion, the tubular wall progressively collapsing toward the opposite end to substantially resiliently close the flow cross-section of the valve means;

said opposite end being intended to be placed in the eosophagus downstream of the fixing portion so that, in use, any force generated on an alimentary bolus by the peristaltic wave of the eosophagus tends to space the resiliently collapsed wall apart, while

any force in the opposite direction tends to prevent gastric reflux through the collapsed end wall as long as it does not exceed a limit substantially greater than that generated by the peristaltic wave of the of the eosophagus and thus causing an at least partial inversion of said tubular shaped valve means.

- 2. The prosthesis of claim 1 wherein the fixing means is an integral extension of the tubular member.
- 3. The prosthesis as defined by claim 1 or claim 2, characterized in that the opposite end of the wall

forms an opening of reduced cross section in the position of repose.

- 4. The prosthesis as defined by any one of claims 1 to 3, wherein the thickness of the wall thins progressively in the direction of said opposite end.
- 5. The prosthesis, substantially as herein described with reference to the drawings.

DATED this 11th day of August, 1992.

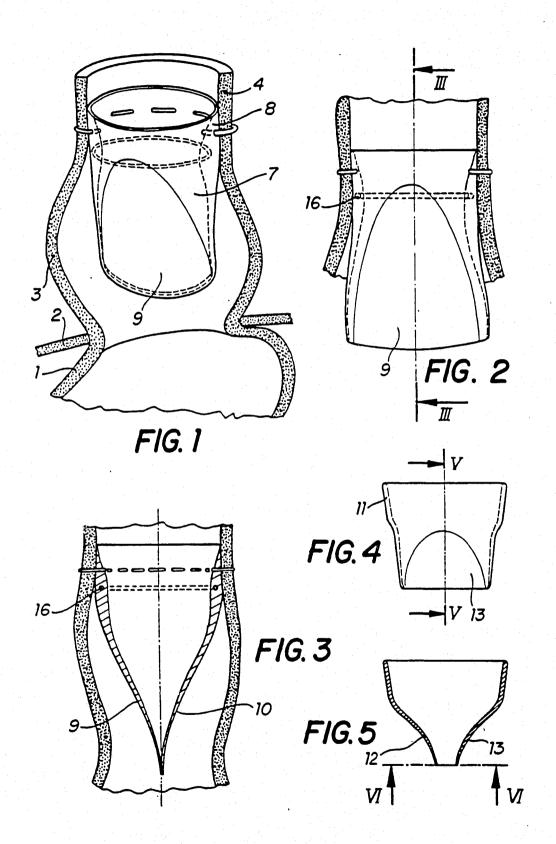
NORMAN GODIN
By His Patent Attorneys
DAVIES COLLISON CAVE

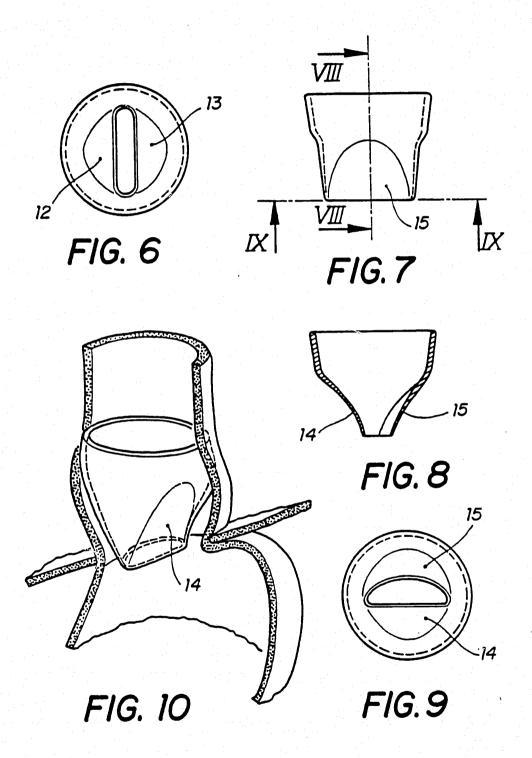


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ABSTRACT OF THE DISCLOSURE

The prosthesis is configured like an anti-return valve arranged preferably in the area where the oesophagus and the hiatal hernia meet. Said valve is comprised of a tubular part associated with an annular fixing element. The tubular part flatens progressively to form two joined lips. It is possible to form said valve with a wall thickness which increases from the free end of the lips towards the annular fixing part in order to avoid an easy returning under the effect of the surging pressure. During the passage of the alimentary bolus, the lips are spaced apart and joined again owing to their natural elasticity. A metal wire embedded in the annular fixing part is used for the radiologic marking.





INTERNATIONAL SEARCH REPORT

International Application No PCT/CH 90/00171

I. CLASS	IFICATION OF SUBJECT MATTER (If several class	ification symbols apply, indicate all) 6	
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II. FIELDS	SEARCHED		
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III. DOCU	UMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of Document, 11 with indication, where an	propriate, of the relevant passages 12	Relevant to Claim No. 13
			
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ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. POTCHUSO 10017

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on

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Patent document cited in search report	Publication date	Patent family memher(s)	Publication date
US-A-4846836	11-07-89	None	
US-A-4265694	05-05-81	US-A- 4222126	16-09-80

FORM POSTS

E For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

RAPPORT DE RECHERCHE INTERNATIONALE PCT/CH 90/00171

Demande Internationale No

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	OFFICE	EUROPEEN DES BREVETS	H. Ballesteros	36

ANNEXE AU RAPPORT DE RECHERCHE INTERNATIONALE RELATIF A LA DEMANDE INTERNATIONALE NO.

Park-190/00171

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La présente annexe indique les membres de la famille de brevets relatifs aux documents brevets cités dans le rapport de

recherche internationale visé ci-dessus. Les dits membres sont contenus au fichier informatique de l'Office européen des brevets à la date du Les renseignements fournis sont donnés à titre indicatif et n'engagent pas la responsabilité de l'Office européen des brevets.

26/11/90

 Document hrevet cité au rapport de recherche	Date de publication	Membre famille de	e(s) de la e brevet(s)	Date de publication
US-A-4846836	4846836 11-07-89	Aucun		
US-A-4265694	05-05-81	US-A-	4222126	16-09-80