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US-A- 4 739 762
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"Modified Gianturco Expandable Wire Stents in Experimental and Clinical Use", J. Rosch, CIRSE, Porto Cervo, Sardinia, May 25-29, 1987, Vol. 31-No. 2, 1987

"Modifications of Gianturco Expandable Wire Stents", Barry T. Ushida, AJR 150:1185-1187, May 1988, American Roentgen Ray Society

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(3.10/3.09/3.3.3)

"Exparimental Intrahepatic Portacaval Anastomosis: Use of Expandable Gianturco Stents", Josef Rosch, M.D., RSNA, 19087, Volume 162 No. 2

"Superior Vena Cava Syndrom Associated with Massive Thrombosis: Treatment with Expandable Wire Stents", RSNA, June 1988

"Gianturce Expandable Wire Stents in the Treatment of Superior Vena Cava Syndrom Recurring After Maximum Tolerance Radiation", Reprinted from CANCER, Vol. 60, No. 6, September 15, 1987

Description

Background of the Invention

This invention relates to stents and in particular, the invention relates to modifications to the Gianturco Expandable Wire Stent.

It is desirable in various situations to provide means for expanding a constricted vessel portion or for maintaining an open passageway through a vessel portion. Such situations arise, for example, in conjunction with arteriosclerosis that restricts or stops blood flow through a vessel, or in conjunction with diseases of the prostrate gland which restrict or stop flow through the urethra.

A percutaneous stent developed by Dr. Cesare Gianturco is formed of a stainless steel wire arranged in a closed, zig-zag pattern, as more fully described in U.S. Patent No. 4,580,568. The Gianturco stent, or the Z-stent as it is also known, is compressed into a reduced size shape with an outer diameter which is many times smaller its outer diameter in an expanded shape. The stent is positioned in a passageway by means of a sheath while the stent is retained in the compressed reduced size shape. A pusher or flat-ended catheter is used through the sheath to hold the stent in place in the passageway while the sheath is withdrawn, thereby allowing the stent to expand in the passageway into its expanded shape to hold the passageway open and enlarged. Thus, the Z-stent provides a self-expanding means for maintaining an open passageway. FIG. 1 illustrates the use of the well-known Z-stent wire within a body passageway.

FIG. 2 illustrates the use of several Z-stents along a limited length of a body passageway. In illustrated arrangement, two stents are situated in an overlapping arrangement, while a third stent is disposed slightly downstream from the other two stents. As discussed more fully in the above-referenced Gianturco '568 patent, each of the three stents must be separately inserted using the sheath and pusher described above.

Since the initial development of the expandable wire Z-stent, it has been discovered that over time a Z-stent may continue to expand to its maximum diameter even though it was originally deployed in a passageway that had a diameter somewhat smaller than the maximum outer diameter of the expanded stent. Thus, the end result has been in some cases that the stent becomes embedded deeply into the walls of the passageway. In an effort to address this particular problem, others in the art have modified the expandable Z-stent to form eyes at the bends or joints of the zig-zag configuration. A monofilament line is then threaded through each of the eyes at one end of the stent to form, in essence, a continuous flexible ring which restricts the expansion of the wire stent. The monofilament line is sufficiently elastic in the tensile direction to control the expansion of the stent to an optimal desired diameter.

Further description of this modified expandable wire Z-stent is found in the following references:

"Modified Gianturco Expandable Wire Stents in Experimental and Clinical Use", J. Rosch, CIRSE, Porto Cervo, Sardinia, May 25-29, 1987, vol 31-No. 2, 1987

"Modifications of Gianturco Expandable Wire Stents", Barry T. Uchida, AJR 150:1185-1187, May 1988, American Roentgen Ray Society

"Experimental Intrahepatic Portacaval Anastomosis: Use of Expandable Gianturco Stents", Josef Rosch, M.D., RSNA, 1987, Volume 162 No. 2

"Superior Vena Cava Syndrome Associated with Massive Thrombosis: Treatment with Expandable Wire Stents", RSNA, June 1988

"Gianturco Expandable Wire Stents in the Treatment of Superior Vena Cava Syndrome Recurring After Maximum-Tolerance Radiation", Reprinted from CANCER, Vol. 60, No. 6, September 15, 1987.

There remains, however, a need for a percutaneous stent that is self-expanding, yet can be retrieved after a period of time of insertion.

According to the invention there is provided a stent assembly comprising:

a first wire formed into a closed zig-zag configuration including:

an endless series of straight sections having opposite ends, said straight sections being joined by bends at said opposite ends to form a stent;

a set of eyes formed at several of said bends at one of said opposite ends; and

a thread passing through successive ones of said set of eyes,

wherein said stent is resiliently contractible into a smaller first shape for conveyance through a body passageway; and

wherein said stent is resiliently expandable into a second shape in which the straight sections press against the walls of the body passageway,

characterised in that said thread includes a pair of free ends, trailing from said stent.

The monofilament thread may be passed through each of the eyes at one end of the stent, once through each of the eyes in a 360° loop and then again 180° through some of the eyes. The trailing free ends of the monofilament preferably leave the stent at opposite sides of the stent diameter and extend through an introducer sheath outside the body passageway. The monofilament can be tied externally to limit the expansion of the self-expanding stent within the body passageway.

The free ends of the monofilament can also be used to reduce the diameter of the stent to permit

retrieval of the stent from the body passageway. Thus, in a method a tube is threaded over the free ends of the monofilament and advanced along the passageway until the tube is adjacent the expanded stent. The free ends are then pulled thereby contracting the outer diameter of the stent until the diameter is approximately equal to the diameter of the tube. A sheath can then be introduced over the tube and over the reduced diameter portion of the stent to further collapse the remaining length of the stent. The entire assembly, including the tube, sheath, stent and monofilament can then be removed from the body passageway.

FIG. 1 is side cross-sectional view of a body passageway with a self-expanding wire stent of the prior art situated therein.

FIG. 2 is a view similar to FIG. 1 showing the use of several stents of the prior art within the body passageway.

FIG. 3 is a side elevational view of a stent known from the prior art documents mentioned above on p.2/l.20 to p.3/l.4.

FIG. 4 is an end elevational view of the structure of FIG. 3.

FIG. 5 is a side elevational view of a multiple stent.

FIG. 6 is a side elevational view of another multiple stent.

FIG. 7A is a side elevational view of still another embodiment of the present invention shown in its expanded state.

FIG. 7B is a side elevational view of the structure of FIG. 7A shown with one end in its contracted state.

FIG. 8 is a sectional view of a body passageway showing a method of insertion of the self-expanding stent of the present invention.

FIG. 9 is a sectional view of the body passageway similar to FIG. 8 following insertion of the self-expanding stent.

FIG. 10A is a sectional view of the body passageway shown in FIG. 9 showing one step of a method of retrieval of the self-expanding stent of one embodiment of the present invention.

FIG. 10B is a view similar to FIG. 10A showing another step of the method of retrieval.

FIG. 10C is a view similar to FIG. 10B showing another step of the method of retrieval of the present invention.

The embodiments of Figs. 5 and 6 are outside the scope of this invention.

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiment illustrated in the drawings and specific language will be used to describe the same.

Referring now more particularly to the drawings, there is illustrated in FIGS. 3-4 a side elevation of a known percutaneous stent 10 which is formed from a length 11 of stainless steel wire formed in a closed zig-zag configuration. The ends of the wire are closed by a sleeve 12 which is welded or tightly squeezed against the ends of the wire to produce a continuous or endless configuration. The length 11 of wire is arranged in a number of side-by-side straight sections 13. Adjacents straight sections 13 of the stents are adjoined by cusps 14.

Up to this point, the stent 10 in most respects, similar to the Z-stent described in U.S. Patent No. 4,580,568. In particular, the specific embodiment of the invention includes the wire 11 which is of stainless steel having a 0,045 cm (0.018 inch) outer diameter. The cusps 14, that is the joint between adjacents straight sections 13, generally circumscribes a radius of no more than 0.2 cm or about .08 inch. As thus configured, the stent 10 is capable of being compressed into a relatively much smaller outer diameter than that shown in FIGS. 3-4, in order to permit insertion of the stent into the body passageway by use of a catheter or sheath.

The cusps 14 of the stent are formed into a number of eyes 20. The eyes may be formed in the continuous wire 11 and the intersection between adjacent straight sections 13 at the cusps 14 are soldered or welded together to provide a closed loop for the eyes 20. The eyes may have a diameter of approximately three times the wire diameter, or about 0,137 cm (.054 inch).

Multiple stents may be combined as shown in Figs. 5 and 6. In FIG. 5, two self-expanding stents 10′ and 10″ are connected or attached at the eyes 20′ and 20″ at the ends of each of the stents. Each of the stents 10′ and 10″ are generally identical to the stent 10 just described. In constructing the union between the two stents 10′ and 10″, the first stent 10′ is formed from a single length of stainless steel wire 11′. The length of wire 11′ is formed into the zig-zag and eye configuration although the cusps 14′ are not immediately soldered. The free ends of the length of wire 11′ are joined by way of the sleeve 12′. Once the first stent 10′ has been formed, the second stent 10″ is formed from a second length 11″ of stainless steel wire. The second length 11″ is formed into the zig-zag and eye configuration so that the eyes 20″ formed at one end of the stent are interlocked with the eyes 20′ of the first stent 10′. Once the second stent 10″ is complete, a sleeve 12″ is used to connect the ends of the length of wire 11′ and the cusps 14′ and 14″ can then be joined or soldered.

A similar method of construction can be used to interconnect a stent 10‴, which is identical to the stent 10 described above, with a single skirt stent 16′, as shown in FIG. 6. In this particular embodiment, the single skirt stent 16′ does not have a

number of eyes defined at the free end of the skirt. The free end of the skirt 16′ may be formed into the configuration of hooks to prevent migration of the stent and skirt combination once the combination is placed within the body passageway. It is understood that in FIGS 5 and 6, the eyes at one end of one stent or skirt may be connected to a stent having only bends or cusps at its connecting end, in a manner similar to the connection between skirt 16′ and a similar skirt 16″ shown in FIG. 6.

In an embodiment of the present invention See Figures 7A and 7B, a stent 30 is formed from a length of wire 31 into a zig-zag configuration identical to the stent 10 shown in FIG. 3. A number of eyes 35 are formed at least at one end of the stent 30. A thread 40, preferably a monofilament of biocompatible material, is passed through successive eyes around the circumference of the expanded stent 30. The thread 40 is passed through the eyes 35 by first passing one end 40a through each successive eye 35 while retaining the other end 40b outside and apart from the stent 30. The first end 40a of the thread 40 is threaded once through each of the eyes 35 in a 360° loop and then 180° further through successive eyes, or about 540° around the circumference of the stent, so that some of the eyes 35 will have two passes of the thread 40 therethrough. Thus, as shown in FIG. 7A, the two free ends 40a and 40b of the thread 40 are situated at 180° opposite eyes 35 of the stent 30. The thread 40 can then be used to collapse one end of the self-expanding wire stent by pulling both free ends 40a and 40b of the thread 40. When the free ends 40a and 40b are pulled simultaneously, the diameter of the thread 40, and therefore the diameter of one end of the stent 30, is decreased. Alternatively, the thread 40 can be used to limit the expanded diameter of the stent by tying the free ends 40a and 40b directly adjacent the stent.

In using the percutaneous stent of the present invention, an insertion technique similar to that described in the Gianturco '568 patent is employed, as shown in FIG. 8. A self-expanding stent 50 includes a number of eyes 55 at each end of the stent 50 and is identical in all respects to the stent 30 shown in FIG. 7A. The monofilament thread 56 passes through the eyes 55 at one end of the stent 50. In the method of insertion, the stent is compressed to its reduced diameter and disposed within a sheath 60, as shown in FIG. 8. The free ends 56a and 56b of the filament 56 extend outside the sheath 60 and exterior to the patient's body for access after the stent has been inserted. For example, when the stent is used as a prostatic stent, the filament 56 has a length of 30 to 40 cm measured from the stent 50 to each of the free ends 56a and 56b, so that the free ends may extend down from the prostate gland to the end of the urethra. When the stent 50 is used as a vascular stent, the length of the filament 56 may be considerably shorter, provided the ends 56a and 56b are situated outside the puncture site and are sufficiently long to be anchored onto the skin nearby.

In the preferred embodiment, the free ends 56a and 56b of the filament 56 are tied together so that they can be easily controlled and maintained. When the stent 50 is compressed within the sheath 60, a pusher 61 is used to hold the stent 50 in position when the body passageway while the sheath 60 is withdrawn. The pusher 61 may have a channel 62 within which the monofilament 56 can be disposed to prevent any pinching or tugging of the filament while the sheath 60 is being removed. Once the sheath is removed, the pusher 61 can also be removed so that the stent 50 remains in position within the body passageway as shown in FIG. 9. The monofilament 56 trails the stent and passes outside the body as described above.

In certain medical operations, the stent 50 need only be positioned temporarily within the body passageway. Thus, in another method, illustrated with reference to FIGS. 10A-10C, the stent 50 is retrieved from the body passageway and removed. In this method, a tube 70 is threaded over the free ends of the monofilament 56 and inserted into the body passageway along the monofilament 56 until it is adjacent the implanted stent 50, as shown in FIG. 10A. Once the tube 70 is positioned directly adjacent the stent 50, the free ends of the monofilament 56 can be pulled through the tube 70, thereby compressing or contracting one end of the stent 50 to a reduced diameter, as shown in FIG. 10B. With the end of the stent 50 thus compressed, a sheath 75 can be introduced into the body passageway over the tube 70, as shown in FIG. 10C. The sheath 75 has an inner diameter larger than the reduced diameter of the end of the stent 50. The sheath 75 is continually conveyed into the body passageway over the tube 70 until it contacts and compresses the remaining length of the self-expanding stent 50. Once the sheath 75 completely covers or shrouds the stent 50, that is when the stent 50 is disposed entirely within the sheath 75, the entire assembly can be removed from the body passageway. In the preferred embodiment of this method, the tube 70 and sheath 75 are composed of medical grade plastic, such as an 8-polyethylene tubing.

Claims

1. A stent assembly (10) comprising:

a first wire formed into a closed zig-zag configuration including:

an endless series of straight sections (13) having opposite ends, said straight sections

being joined by bends (14) at said opposite ends to form a stent;

a set of eyes (20) formed at several of said bends at one of said opposite ends; and

a thread (40) passing through successive ones of said set of eyes,

wherein said stent is resiliently contractible into a smaller first shape for conveyance through a body passageway; and

wherein said stent is resiliently expandable into a second shape in which the straight sections press against the walls of the body passageway,

characterised in that said thread includes a pair of free ends (40a, 40b), trailing from said stent.

2. The stent assembly of claim 1, wherein:

said second shape of said stent includes a circumference at said one of said opposite ends, said set of eyes being situated at said circumference; and

said thread passes through successive eyes (20) at least 360° around said circumference.

3. The stent assembly of claim 2, wherein said thread passes through successive eyes (20) approximately 540° around said circumference.

4. The stent assembly of claim 1, wherein said free ends (40a, 40b) are sufficiently long to extend outside the body passageway when said stent is situated within the passageway.

5. The stent assembly (10) of claim 1, further comprising:

a second wire (11'') formed into a closed zig-zag configuration including:

a second endless series of straight sections having opposite ends, said straight sections being joined by bends (14'') at said opposite ends to form a second stent;

a second set of eyes (20'') formed at several of said bends at one of said opposite ends;

wherein said second stent is resiliently contractible into a smaller first shape for conveyance through a body passageway;

wherein said second stent (10'') is resiliently expandable into a second shape in which the straight sections press against the walls of the body passageway; and

wherein said second set of eyes (20'') of said second wire are engaged about said first wire (11') at one of said opposite ends.

6. The stent assembly of claim 5, wherein:

said first wire (11') includes a third set of eyes formed at several bends at the other of said opposite ends of said first wire; and

said second set of eyes of said second wire are interengaged with said third set of eyes.

Patentansprüche

1. Eine Dilatator- oder Stent-Anordnung (10) aufweisend:

einen ersten in geschlossene Zick-Zack-Konfiguration gelegten Draht, aufweisend

eine endlose Serie von gestreckten oder geraden Abschnitten (13) mit gegenüberliegenden Enden, wobei die geraden Abschnitte über Biegestellen (14) an den gegenüberliegenden Enden verbunden sind, um einen Stent zu bilden;

einen Satz von Öhren (20), die an einigen der Biegestellen an dem einen der gegenüberliegenden Enden ausgebildet sind, und

einen Faden (40), der durch aufeinanderfolgende Sätze der Öhre hindurchgeht,

wobei der Stent in eine kleinere erste Form zum Transport durch einen Körperdurchgang nachgiebig zusammenziehbar ausgebildet ist;

und wobei der Stent in eine zweite Form nachgiebig aufweitbar ausgebildet ist, in welcher die geraden Abschnitte gegen die Wände des Körperdurchganges drücken,

dadurch gekennzeichnet, daß der Faden ein Paar freie Enden (40a, 40b) hat, die von dem Stent weggerichtet sind bzw. diesem folgen.

2. Die Stent-Anordnung nach Anspruch 1, in welchem

die zweite Form des Stents einen Umfangsteil an dem einen der sich gegenüberliegenden Enden aufweist, wobei die Öhre an diesem Umfangsteil angeordnet sind; und

der Faden durch aufeinanderfolgende Öhre (20) hindurch über wenigstens 360° um den Umfangsteil herum verläuft.

3. Die Stent-Anordnung nach Anspruch 2, wobei der Faden durch aufeinanderfolgende Öhre (20) um ungefähr 540° um dem Umfangsteil herum läuft.

4. Die Stent-Anordnung nach Anspruch 1, worin die freien Enden (40a, 40b) ausreichend lang ausgebildet sind, um aus dem Körperdurchgang herauszureichen, wenn der Stent innerhalb des Durchganges angeordnet ist.

5. Die Stent-Anordnung (10) nach Anspruch 1x, weiterhin aufweisend:

einen zweiten Draht (11''), welcher in eine geschlossene Zick-Zack-Konfiguration gebildet ist und aufweist:

eine zweite endlose Serie von geraden Abschnitten mit gegenüberliegenden Enden, wobei die geraden Abschnitte durch Biegestellen (14'') an den gegenüberliegenden Enden verbunden sind, um einen zweiten Stent zu bilden;

einen zweiten Satz von Öhren (20'') die an einigen der Biegestellen an dem einen der gegenüberliegenden Enden ausgebildet sind;

worin der zweite Stent in eine kleinere erste Gestalt zum Transport durch einen Körperdurchgang nachgiebig zusammenziehbar ausgebildet ist;

wobei der zweite Stent (10'') in eine zweite Form nachgiebig aufweitbar ausgebildet ist, in welcher die geraden Abschnitte sich gegen die Wände des Körperdurchganges pressen; und

wobei der zweite Satz von Öhren (20'') des zweiten Drahtes um den ersten Draht (11') herum an dem einen der gegenüberliegenden Enden im Eingriff angeordnet ist.

6. Die Stent-Anordnung nach Anspruch 5, wobei

der erste Draht (11') einen dritten Satz von Öhren aufweist, die an verschiedenen Biegestellen an dem anderen der gegenüberliegenden Enden des ersten Drahtes ausgebildet sind und

der zweite Satz von Öhren des zweiten Drahtes in Zwischeneingriff mit dem dritten Satz von Öhren angeordnet ist.

Revendications

1. Un ensemble dilatateur (10) comprenant :

un premier fil métallique formé selon une configuration en zig-zag fermée comportant :

une série sans fin de sections droites (13) ayant des extrémités opposées, lesdites sections droites étant réunies par des coudes (14) auxdites extrémités opposées pour former un dilatateur ;

un jeu d'oeillets (20) formés sur plusieurs desdits coudes à une première desdites extrémités opposées ; et

un fil (40) passant au travers des oeillets successifs dudit jeu d'oeillets,

dans lequel ledit dilatateur est susceptible d'être contracté élastiquement selon une première configuration plus petite pour être acheminé au travers d'un passage corporel ; et

dans lequel ledit dilatateur est susceptible d'être dilaté élastiquement selon une deuxième configuration dans laquelle les sections droites appuient contre les parois du passage corporel,

caractérisé en ce que ledit fil comprend deux extrémités libres (40a, 40b) traînant à partir dudit dilatateur.

2. L'ensemble dilatateur selon la revendication 1, dans lequel :

ladite deuxième configuration dudit dilatateur présente une circonférence sur ladite première extrémité desdites extrémités opposées, ledit jeu d'oeillets étant situé sur ladite circonférence ; et

ledit fil passe au travers des oeillets successifs (20) au moins sur 360° autour de ladite circonférence.

3. L'ensemble dilatateur selon la revendication 2, dans lequel ledit fil passe au travers des oeillets successifs (20) sur approximativement 540° autour de ladite circonférence.

4. L'ensemble dilatateur selon la revendication 1, dans lequel lesdites extrémités libres (40a, 40b) sont suffisamment longues pour s'étendre à l'extérieur du passage corporel lorsque ledit dilatateur est disposé dans ledit passage.

5. L'ensemble dilatateur (10) selon la revendication 1, comprenant, en outre :

un deuxième fil métallique (11'') formé selon une configuration en zig-zag fermée comprenant :

une deuxième série sans fin de sections droites ayant des extrémités opposées, lesdites sections droites étant réunies par des coudes (14'') auxdites extrémités opposées pour former un deuxième dilatateur,

un deuxième jeu d'oeillets (20'') formés sur plusieurs desdits coudes à l'une desdites extrémités opposées ;

dans lequel ledit deuxième dilatateur est susceptible d'être contracté élastiquement selon une première configuration plus petite pour être acheminé au travers d'un passage corporel ;

dans lequel ledit deuxième dilatateur (10'') est susceptible d'être dilaté élastiquement selon une deuxième configuration dans laquelle les sections droites appuient contre les parois du passage corporel ; et

dans lequel les oeillets dudit deuxième jeu d'oeillets (20'') dudit deuxième fil métallique sont enfilés autour dudit premier fil métallique (11') à l'une desdites extrémités opposées.

6. L'ensemble dilatateur selon la revendication 5, dans lequel :

ledit premier fil métallique (11') comprend un troisième jeu d'oeillets formés sur plusieurs coudes à l'autre desdites extrémités opposées dudit premier fil métallique ; et

Les oeillets dudit deuxième jeu d'oeillets dudit deuxième fil métallique sont en prise mutuelle avec ledit troisième jeu d'oeillets.

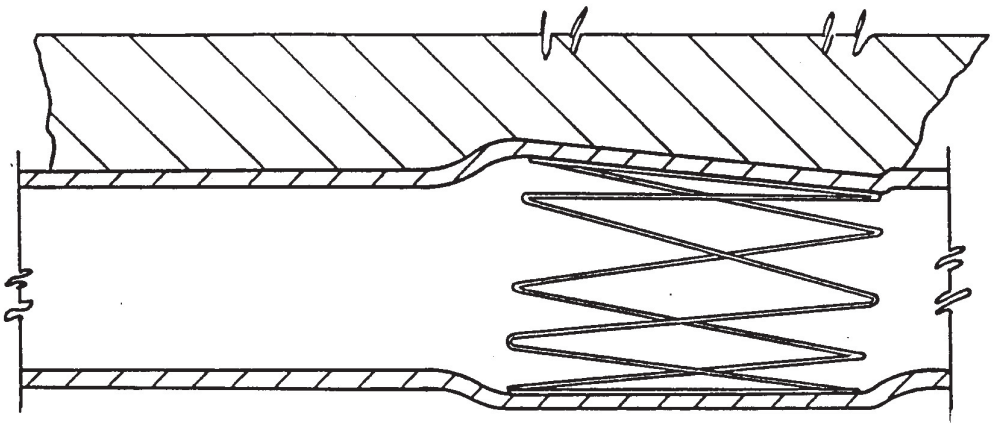

Fig.1
PRIOR ART

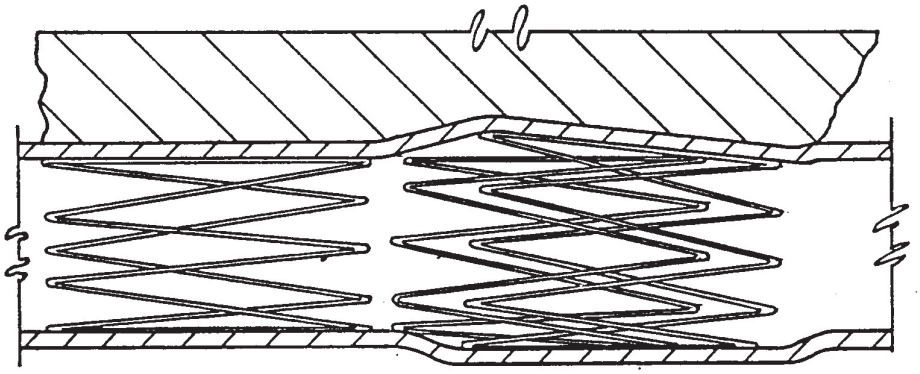

Fig.2
PRIOR ART

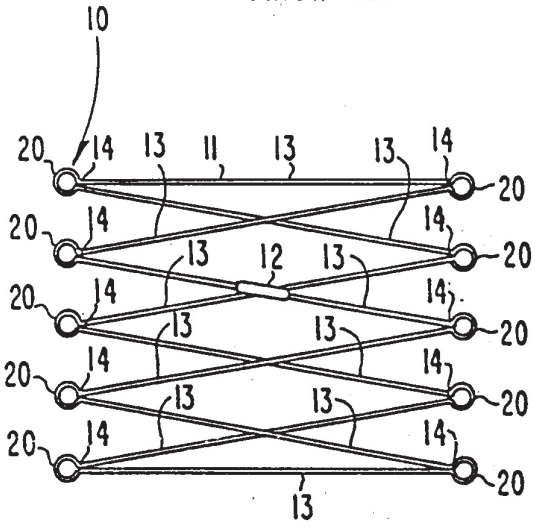

Fig.3

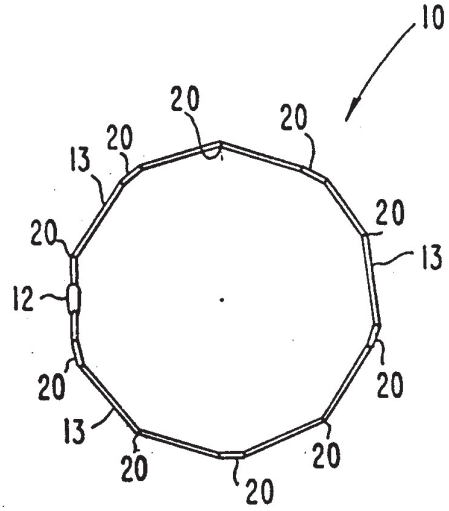

Fig.4

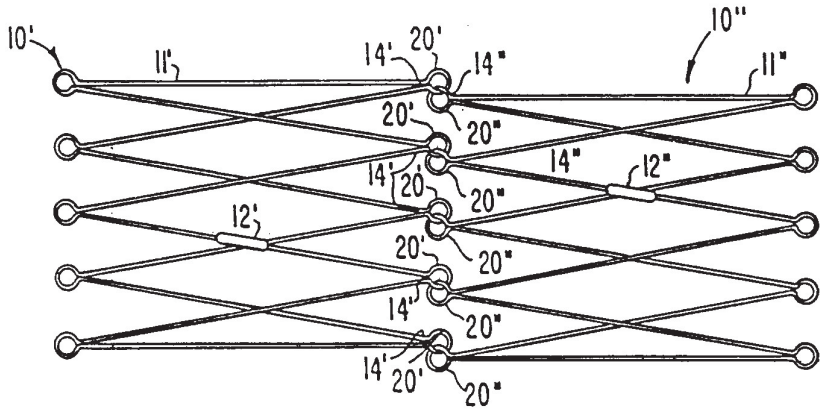
10'
11'
14'
20'
14"
10"
11"
20'
20"
14'
20'
20"
14"
12"
12'
20'
20"
14"
20"
14'
20'
20"

Fig.5

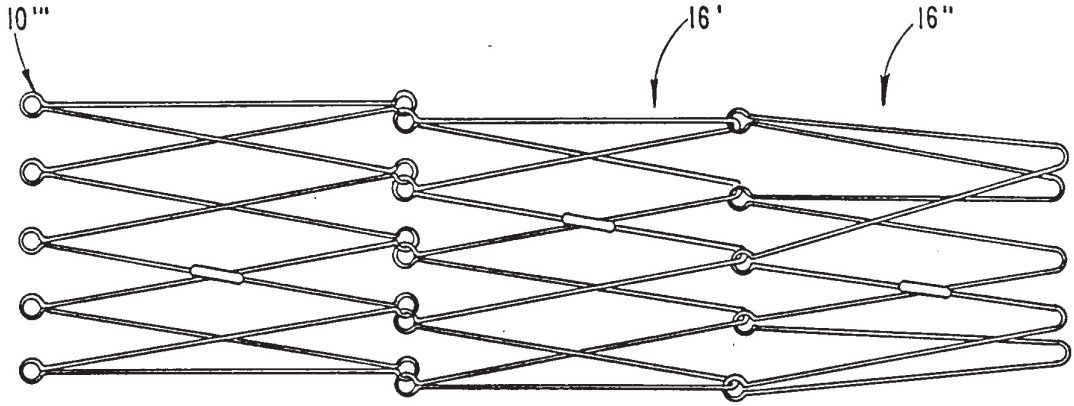
10'''
16'
16"

Fig.6

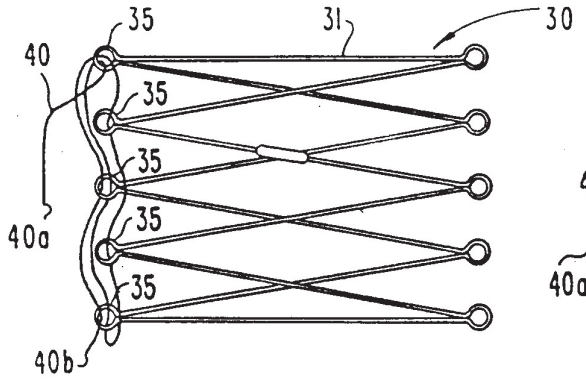

Fig.7A

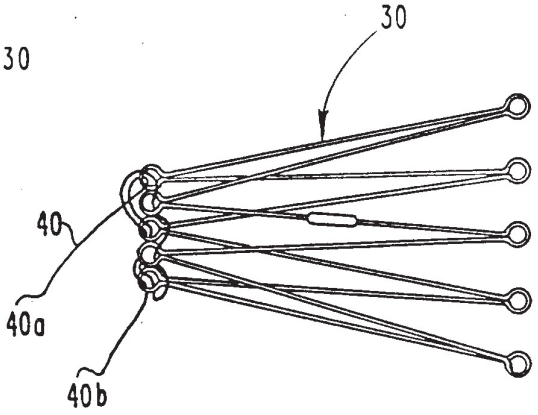

Fig.7B

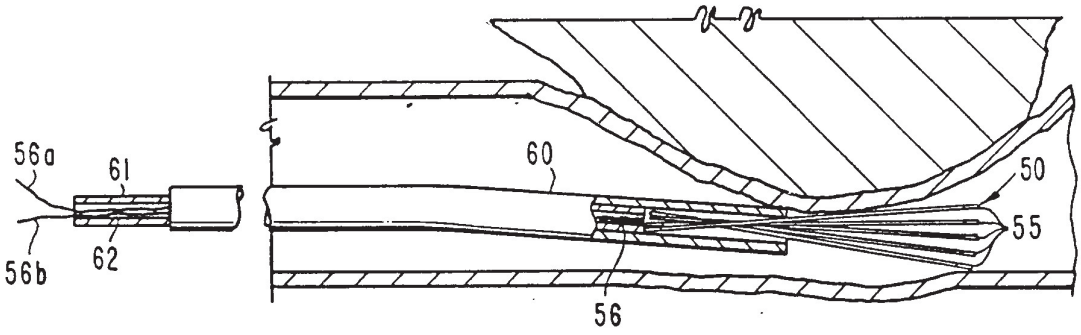

Fig.8

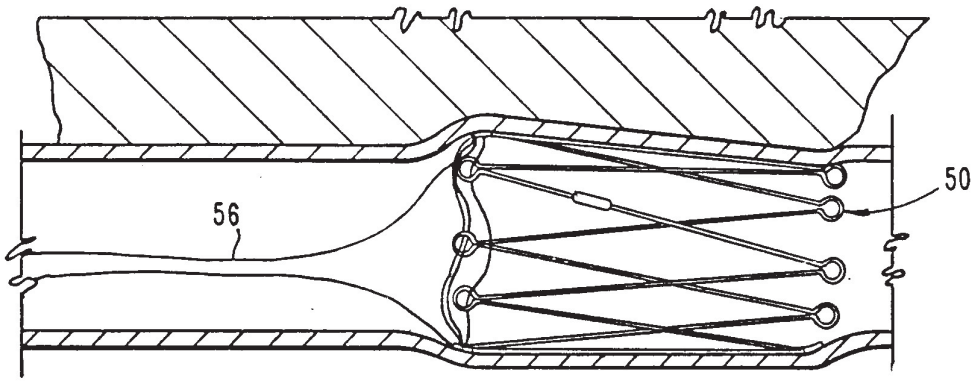

Fig.9

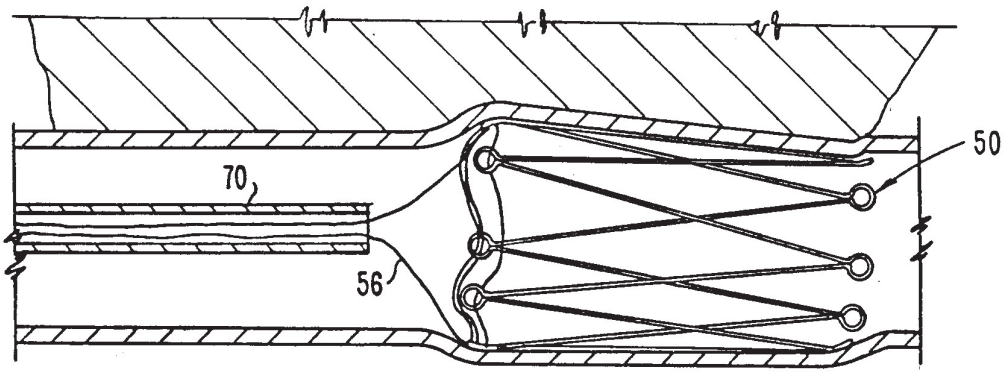

Fig.10A

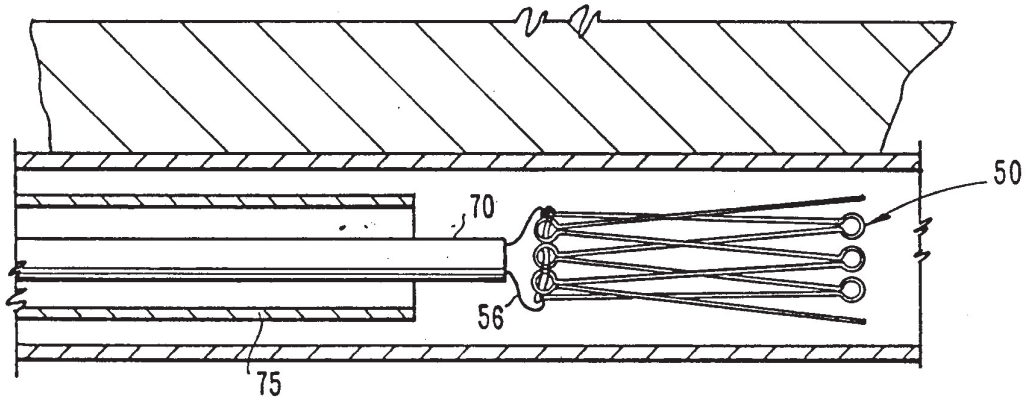

Fig.10B

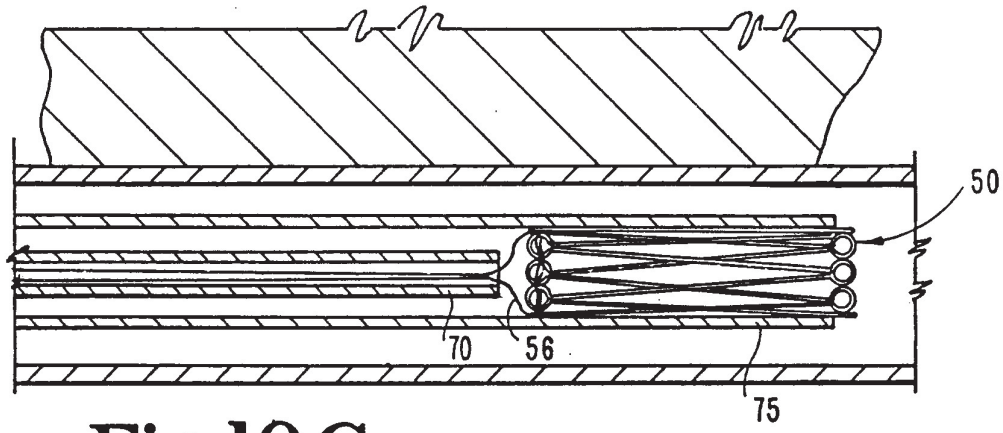

Fig.10C