July 28, 1964 W. J. LIEBIG 3,142,067

SYNTHETIC VASCULAR IMPLANTS

Original Filed Nov. 21, 1958

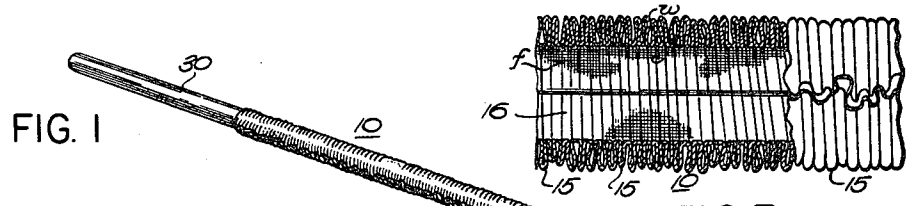

FIG. 1

FIG. 7

FIG. 2

FIG. 3

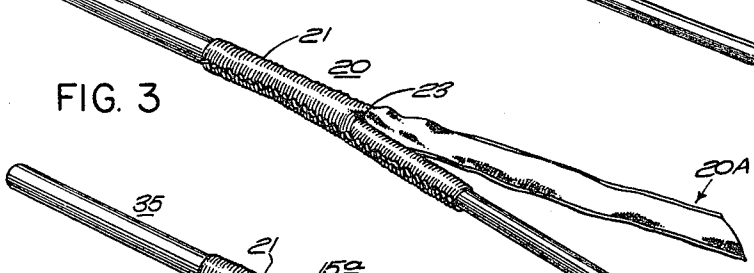

FIG. 4

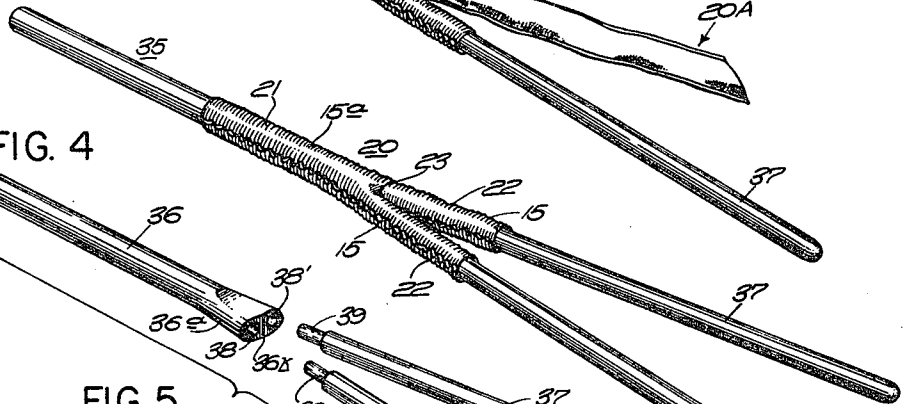

FIG. 5

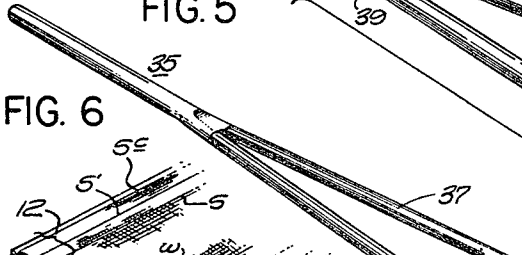

FIG. 6

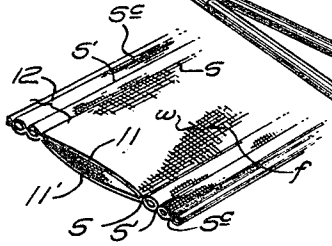

FIG. 8

INVENTOR.
WILLIAM J. LIEBIG
BY
Emery, Booth, Miller & Townsend
ATTORNEYS

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SYNTHETIC VASCULAR IMPLANTS

William J. Liebig, Martha Road, Harrington Park, N.J.

Original application Nov. 21, 1958, Ser. No. 775,522, now Patent No. 3,096,560, dated July 9, 1963. Divided and this application Feb. 16, 1961, Ser. No. 89,862
3 Claims. (Cl. 3—1)

This invention concerns vascular prostheses and aims to provide for such devices as improved flexible and resilient self-supporting tubular wall structure which affords a normal open form for the prosthetic tube defined thereby and in which form it is supple and plaint as to flexure capacity, is extensible and contractible elastically lengthwise, and has the property of automatic return to the open form with little or no remnant deformation upon release of bending, compressive or other distorting stress.

This application is a division of my copending application Serial No. 775,522, filed November 21, 1958, now Patent No. 3,096,560.

The invention is more particularly pertinent to non-sewn tubular woven synthetic vascular implants such as fully disclosed and claimed in my copending application Serial No. 653,562, filed April 18, 1957, now Patent No. 2,978,787. It generally improves thereon by correlating with the all-woven basic tubular body formation thereof a determined lateral and circumferential wall modification presenting a smooth interior and a finely folded exterior structure herein sometimes termed "micro-crimping," having reference both to the method and to the resultant formation.

In the drawings illustrating certain embodiments of the invention:

FIG. 1 shows a single-tube woven implant and forming mandrel at an intermediate stage of micro-crimping;

FIG. 2 shows a further stage in the processing, with the implant fully installed on the mandrel and reduced to final normal length;

FIGS. 3 to 6 illustrated the product, method and means as to a vascular implant of bifurcated form, wherein

FIG. 3 shows an intermediate stage corresponding generally to that of FIG. 1;

FIG. 4 represents a further stage like that of FIG. 2;

FIG. 5 shows separately a mandrel such as used for bifurcate implants, with legs thereof demounted;

FIG. 6 on a smaller scale shows the mandrel of FIG. 5 assembled;

FIG. 7 is an elevational view of a length of implant of the invention, such as that of FIGS. 2 to 4, with a portion sectioned to show the generally smooth internal wall surface as presented by the multiplicity of narrow close-abutted woven fabric rings thereat; and

FIG. 8 is a partly diagrammatic perspective of an end portion of an implant fabric blank unit such as of FIGS. 1 and 3 before micro-crimping.

Referring to the drawings in more detail the vascular prostheses or implants of this invention are basically fabricated by weaving them in flat tubular form upon a specially modified Jacquard loom so that a plurality of fine dense fabric plies are interwoven along longitudinal integral union zones, the resultant continuous tubular non-sewn bodies being composed of multi-filament circumferential warp and longitudinal filling strands.

These implants may have various overall forms of which two main categories are herein illustrated. FIGS. 1 and 2 show an implant of the single-tube, simple or straight-line form, designated as a whole at **10**. FIGS. 3 and 4 show an important divided, bifurcate or Y-form, indicated as a whole at **20**.

An implant **10**, at an intermediate stage following severance from the larger fabric blank that comes from the loom, is seen at the right in FIG. 1, in more or less flat-

tened or partly open condition, as indicated at **10A** and similarly at **20A** in FIG. 3; see also FIG. 8. It comprises superposed woven fabric plies **11**, **11'** integrally joined in longitudinal non-sewn flange-like seams or seal-formations **12** along diametrically opposite longitudinal portions. These axis-paralleling unions or seal-formations **12** are composite non-sewn integral fabric structures interwoven as part of the tubular implant body as a whole. Each contains a dual-ply fabric area demarked from the adjoined main tubular portion by sealing lines of union where the constituent warp is cross-shedded, as at S, S' and S^c, FIG. 8.

As noted, an implant unit such as **10** of FIGS. 1 and 2 is severed from others initially in the same plural-ply woven fabric web. The severance is along a cross-shedded line of ply union such as S^c of FIG. 8 spaced by at least one other such union line from the adjoined main tubular area of the fabric; see such lines S and S' in FIG. 8. Along the severance line S^c the component synthetic multi-filament yarns are heat-sealed as by a heated severing instrument to afford a fused seal in addition to the one or more in-woven lines of union contained in the entirety of each of the respective integral longitudinal unions or seal formations **12**. The foregoing description of the non-sewn woven tubular fabric along with the present drawings is adequate for the purposes of this application and is as disclosed in greater detail in my mentioned copending application.

As in said earlier application the woven tubular unit blanks as at **10A** and **20A** are composed of fine-denier multi-filament synthetic warp and filling yarns of materials selected for desired vascular implant properties. These include compatability with human tissue along with wettability for blood such as to promote the starting of clotting and the attendant growth of a layer of collagen on the wall of the prosthetic tubing after implantation, and further include strength, flexibility and resilience, appropriate water-absorptivity and capacity to withstand sterilization. The multi-filament yarn found most satisfactory to date is a terephthalic acid-ethylene glycol ester as commercially produced by Du Pont de Nemours Co. under the trademark Dacron. Some of the desired characteristics are present in other commercially available synthetic fibres including the long-chain polyamide type of the nylon class, those of the tetrafluoroethylene type known under the trademark Teflon, also the type commercially designated as Orlon. In the presently preferred example the weaving is accomplished with a 34-filament Dacron yarn of approximately 70 denier as for example that known commercially as Du Pont Type 56 (formerly called 5600), received from the manufacturer with zero twist and preparatorily to weaving given a relatively soft twist as for example about a 9 to 12 turn left or **Z** twist for warp and about a 5 turn left **Z** or right **S** twist for filling.

In accordance with the invention, wherein the porosity of the fabric is a function both of the size and of the multi-filament nature of the yarns as well as of the close proximity of the yarns as laid in the weaving operation, an extremely close or dense weave of the selected yarns is needed for the relatively low order of porosity here concerned, desirably not less than 16 nor greater than about 25 to 30 porosity in terms of cubic feet of air per minute through a square foot of the fabric at a pressure of 1.26 in. of water. Utilizing as preferred example a 70 denier 34-filament Dacron yarn, suitable fabric fineness, density and porosity is obtained when each cloth or ply of the dual-layer fabric has a count in the order of 150 or more warp ends by 100 or more filling picks per inch in a plain or so-called taffeta weave, the loom generally employing in the two cloths or plies a total of over 300 warp ends by 200 picks per inch, in one ex-

ample 168 warp ends by 108 filling picks per inch. Further by way of specific example but without limitation thereto a specially modified Jacquard loom in one case of actual practice weaves a 50-inch web incorporating a sheet of 15,360 warp ends appropriately divided for shedding into two warp sets, the integral unions of the fabric plies as above mentioned being accomplished by causing the respective warp sets to "cross over" as appropriate for the shape and dimension of the particular tubular implant desired.

On the accompanying drawing the multi-filament warp yarns, extending circumferentially of the tube are designated at *w* and the similar filling yarns, lengthwise of the tube, at *f*, FIGS. 1, 3, 7 and 8.

The resultant woven integrally sealed non-sewn tubular elements or implant units at **10**A and **20**A hereof, following doffing of the fabric web from the loom and severance of the individual implant units as already described are under the present invention accorded the further processing whereby the finished tubular products incorporate markedly improved characteristics as to lateral flexibility and resilience and axial elastic extension coupled with the capacity of self-support in and self-return to open tubular form.

In such processing I employ forming and ironing mandrels of generally cylindrical rod form and of metal or other material adapted for heating and free of objectionable chemical or contaminant effect on the tubular fabric blanks received thereon. Preferred materials include stainless steel and chemically pure anodized aluminum.

For the single-tube form of FIGS. 1 and 2 the mandrel **30** is a straight rod of circular cross-section having at one or both ends a rounded nose as at **31**. Each such mandrel **30** is accurately scaled to an outer diameter closely matching the inner diameter for the particular size of implant in the finished inflated or open status. The mandrels, which are provided with a smooth hard outer surface, accordingly are made of lumen-filling dimension with respect to the tubular implant units. Typical examples for the straight or single-tube implants of FIGS. 1 and 2 are as follows:

Straight Tubes

	Flat Diameter, mm.	Open Diameter, mm.
1	7.86	5
2	9.43	6
3	11.00	7
4	12.57	8
5	14.14	9
6	15.71	10

The values in the right-hand column under "Open Diameter" are the lumen size of the ready-for-use implant in relaxed status. The mandrel diameter at room temperature is closely scaled to the lumen of the particular implant.

Having furnished and selected the appropriate mandrel **30** the woven tubular implant blank **10**A preferably moistened in a water bath is passed and collected in a moist state onto the mandrel received snugly within it. The fabric blank is axially compressed on the mandrel **30** so that it is condensed to approximately 25% of the original length of the blank. This is accomplished mechanically or by by hand, the foremost end of the blank being passed along over the mandrel to a distance from the receiving end thereof at least equal to the final condensed length of the implant. In FIG. 1 the blank **10**A is shown in progression onto the mandrel **30** and in the course of being compressed. In FIG. 2 the compressive approximate 4:1 length reduction has been completed.

This operation of compressing the moistened fabric blank onto the mandrel creates at the same time a longitudinal array of minute circumferential pleats or crimps **15** upon the tubular fabric wall, shown on an enlarged scale in FIG. 7 and seen more or less diagrammatically in each of FIGS. 1 to 4. These pleats **15** are wholly external to the inner circumferential surface of the tubular implant as compelled by the filling diameter of the forming mandrel **30**. Under the stated 4 to 1 compressive axial reduction the two radial walls of each individual pleat or crimp **15** are approached to each other into largely closed or random touching proximate contiguity, particularly at the basal portions. Also in the longitudinal array as a whole the multiplicity of minute pleats or crimps **15** which I term "micro-crimping" are closely compacted one with the next in somewhat re-entrant or partially interfitting relation in a closed rank or stack.

Noting particularly FIG. 7, the short pleats or crimps **15** of the multiplicity thereof are of uneven outward radial extent and individually vary in cross-sectional contour. While the outward radial extent of the micro-crimping is a function of the diameter of the implant tube and of the mandrel, increasing with the tube diameter, the exact shaping thereof is random and without deliberate mechanical or measured distribution into a certain number of crimps per inch or into absolute regularity in radial extent and area. Otherwise stated, the micro-crimping is that resultant from and characterized by axial compressive reduction of the tubular fabric blank in a moist state to approximately 25% of the original length in conjunction with installation upon a smooth hard-surfaced incompressible mandrel of full scale or filling size equivalent to the desired lumen for the particular tubular implant product.

Further, in the described micro-crimping procedure the plural-ply radially projective longitudinal seal formations **12** automatically accommodate themselves to the close fine pleating **15** of the tube body. They likewise assume a random compressed, pleated or ruffled form with the crests of the pleats some to one side and some to the other side of the original longitudinal line of sealing union along the tube body, in oppositely offset relation with respect to that line, in a manner resembling a positive and negative curve along a zero reference line. Also the fabric of the seal formations **12** is in major part external to the crests of the body pleats **15**. Thus these seal formations **12** conform themselves to the same proportionate approximate 4 to 1 length reduction as for the tubular body portion, noting particularly the elevational portion of FIG. 7. These micro-crimped seal zones **12** while importing little or no decrease in flexibility, lateral resilience or axial elasticity for the resulting tubular implant as a whole, contribute to the overall capacity of the implant for self-maintenance in a normal open condition and for return thereto on removal of deforming force.

Referring again to FIG. 7 showing a completed implant the interior thereof presents a cylindrical surface defined by a multiplicity of uniform-diametered inwardly smooth rings **16** of like number as that of the pleats or crimps **15** and spanning between them in mutually touching side by side relation over the entire longitudinal extent of the implant tube in the normal or relaxed state of the final product. In completing the processing these internal wall-defining rings **16** are in effect internally ironed to present a smooth cylindrical wall surface wholly uninterrupted circumferentially and being effectively closed or continuous longitudinally in the normal unstressed status of the tubular device.

With the tubular fabric unit installed in a moist state and fully compressed to ultimate reduced length as in FIG. 2 or 4, the carrying mandrel **30** or **35** is inserted into an oven where it is located over a water bath and is heated to a temperature determinately below the melting point of the component synthetic yarns. In the preferred instance of Dacron for example, having a melting point of 480° F., the oven temperature is held to not exceeding about 425° F., the fabric thus being subjected to a slightly moist heat over the water bath in

the oven. Under this treatment the metallic mandrel **30** tends to expand and accordingly imparts to the inner interpleat rings **16** a further smoothing or ironing action and resultant substantially uniform cylindrical inner surface for the device as a whole. This ironing heat and moisture treatment is of short duration accurately timed for optimum effect. In practice the best timing is found to be approximately 15 minutes, any variation therefrom desirably being not more than about one and one-half minutes plus or minus.

At the end of the controlled heating period the mandrel and micro-crimped implant unit thereon are removed from the oven and placed into a relatively cool water bath at approximately 70° F., or substantially room temperature for a cooling period of about five minutes. This cools and shrinks the mandrel and is believed to have some beneficial adjustive or relaxing effect upon the component synthetic yarns and the multi-filaments thereof. Following the coolant water bath the implant unit such as **10** of FIGS. 1 and 2 is removed from the mandrel and allowed to dry at room temperature.

The process as above described with reference to a single-tube or straight tubular implant **10** is generally similar for the bifurcate or Y-form of FIGS. 3 to 6. For this divided or plural tube form a special conformant mandrel is provided, indicated as a whole at **35**, shown separately on a smaller scale in FIG. 6, in disassembled or preparatory condition in FIG. 5 and in use in FIGS. 3 and 4.

It will be understood that bifurcate implants **20**, FIGS. 3 and 4, are useful for replacement of vascular junctures, especially that of the large abdominal aorta and its division into the iliac limbs. Such Y-form implant **20** accordingly is formed with a stem or aortic portion **21** usually of relatively larger diameter and having at one end the iliac branches or legs **22, 22.**

The plural-ply tubular fabric blank for this bifurcate form **20** is woven of the synthetic multi-filament warp and filling yarns in similar manner as already explained. Each of the woven tubular portions **21, 22, 22** is structurally similar to that of the single-tube implant of FIGS. 1 and 2 and as represented in detail in FIGS. 7 and 8 with the added feature of the branching and angling tubular structure. Thus in weaving the iliac legs **22** and the crotch or juncture thereof with the aortic stem **21**, there is effected a calculated changing of the location of the cross-over lines of union S, S′ and S^c in the fillingwise direction for each pick or a small number of picks in each of the two plies. Under the patterned control of the shedding the legs **22, 22** are accorded the desired diameter and angular relation and the crotch area including the extreme point of the Y is integrally woven as a closed fabric structure of equal density with that at all other fabric areas, such that undesired leakage at the bifurcation point and adjacent region is obviated.

The bifurcate mandrel **35**, FIGS. 3 to 5, is of similar composition and dimensioning relative to the implant blanks as described in connection with FIGS. 1 and 2. In this instance however it is so articulated that the stem section **36** and one or both leg sections **37, 37** are relatively detachable. While for some uses one leg **37** may be integral with the stem **36**, it is found generally preferable that both legs be demountable as shown.

Separability is herein afforded as by provision of interconnecting plug and socket formations at the joints of the mating mandrel sections. In the illustrated example the stem **36** has at the end adjacent and containing the point of leg branching an appropriately flared and correspondingly flattened yoke **36*a***. Longitudinal sockets **38, 38** are let in from the transverse end wall of the yoke **36*a***, the sockets being relatively inclined at the angle desired for the mandrel legs **37**. The socketed areas of the end wall of the yoke **36*a*** are preferably disposed to be accurately perpendicular to the leg axes. At the proximate ends the mandrel legs **37, 37** are reduced to provide pins **39, 39** adapted for tight seating in the corresponding sockets **38, 38**. The parts are accurately machined and finished so that the leg shoulders at the base of the pins tightly abut the end wall of the stem yoke **36*a*** and the cylindrical outer walls of the legs flow substantially without interruption into the circumferential surface of the stem **36** and its yoke **36*a***. The flattening of the latter across the flared portion is made to compensate for the flare; that is, the circumference at the yoke **36*a*** is kept at or not materially greater than for the main cylindrical portion of the stem **36** so that little or no distention of the tubular fabric blank occurs in the micro-crimping operation.

For vascular implant purposes the iliac legs of a Y-form implant generally are each smaller in diameter than that of the aortic stem but in the practice of the invention they may approach or substantially equal that of the aortic stem. In some instances it is required that the two legs differ in diameter from each other in which case the Y-form tubular blanks are woven to the desired diameters.

Examples of diameter values for bifurcate implants fabricated under the invention include the following in actual practice:

Tubular Bifurcations

	Aortic		Iliac	
	Flat Diameter, mm.	Open Diameter, mm.	Flat Diameter, mm.	Open Diameter, mm.
1	22.3	14.6	15.3	10.0
2	29.9	19.0	18.3	12.4
3	44.6	28.7	23.1	15.2
4	44.6	28.7	39.5 and 23.4	27.6 and 15.8
5	52.2	33.3	23.1	15.8
6	52.2	33.7	30.3	19.4
7	59.8	38.3	23.4	15.0
8	59.8	38.2	31.0	20.0
9	37.6	24.0	18.7	1

The "open diameter" values in the above table are also the diameter of the corresponding mandrels at room temperature.

As in the case of the single-tube implants the Y-form mandrel diameters, for the aortic stem **36** and for the iliac legs **37, 37** are scaled to have at room temperature diameter sizes the same as the lumen or open diameter values such as above indicated. It is noted that implant item No. 4 of the above table has iliac limbs differing from each other in diameter; also that implant items Nos. 5 and 6 and also Nos. 7 and 8 show instances of a given same size of aortic stem available with different sizes of legs.

In any instance the bifurcate mandrels such as **35** are accurately scaled as to stem and leg diameter to that desired for the particular implant. And in any instance the mandrels **35** are so constructed, having reference to the leg diameters relative to the stem and to each other that the two legs are sufficiently spaced at the point of juncture with the mandrel stem so that the tubular fabric of the respective legs can be compressively installed fully to the end wall of the stem yoke **36*a***.

In the compressive installation of a Y-form implant blank **20A** onto a mandrel **35** the procedure is generally similar as described with respect to the straight form blank of FIGS. 1 and 2. Where both mandrel legs are demountable the legs of the fabric blank may be brought onto them in either direction accordingly as the blank stem is installed before or after the blank legs. More conveniently the blank stem is first compressed onto the mandrel stem **36** at the yoke end **36*a*** of the latter and the mandrel legs **37, 37** then inserted through the blank legs, set into the stem sockets **38** and the compressive micro-crimping completed for the entire blank. Obviously with

one mandrel leg integral the fabric blank is installed by first passing the stem of the blank over the integral leg of the mandrel.

The operation of mounting the blank on the mandrel again is accomplished with attendant axial compression such that the blank is reduced to the approximate 25% of the overall initial length. In the area of the crotch at the junction of the legs with the stem the micro-crimping is substantially continuous, with the innermost pleats **15** of the leg members merging directly into the pleats **15***a* of the stem, with the fabric of the first stem pleat brought radially inward centrally between the legs into conformity with the end wall of the stem yoke **36***a* and affording crotch-closing fillets uniting all three tubular elements of the implant. Such fillet or crotch-closing wall portion is seen at **23**, FIGS. 3 and 4. It has a general hour-glass shape corresponding to the central inter-socket area **36***x* of the mandrel yoke **36***a*, FIG. 5.

By way of additional precaution at the area of maximum vulnerability to leakage under abnormal conditions, the Y-form implants **20** after being thoroughly dried following the processing as described in connection with FIGS. 1 and 2 are coated at the crotch area with an aqueous solution of polyvinyl and allowed to air dry. Thereafter the coated area is cured as by placing the implant in an oven at about 250° F. for a period to average about five minutes.

The prosthetic implants **10** and **20** as herein disclosed possess such flexibility and resilience that they are free of kinking, objectionable stricture or collapse not only under flexure of the shorter lengths of 15 cm. and 20 cm. through a full 360° of bend but such length can be tied into a throw-knot or given a full twist between the ends and will still maintain an open lumen. They possess the further advantage among others that they can be supplied not only as units fashioned to exact surgical specifications but also in extra or indefinite lengths for cutting to proper lengths in the operating room. Likewise an implant of specified length may if required be extended axially for additional attaching length even in the course of operative implantation.

The resultant vascular implants of the invention are showing excellent results both in animal and in clinical work in which they have been used to replace segments of the aorta and/or peripheral arteries, or as shunts, thereby importantly contributing to progress in the field of cardiovascular surgery.

My invention is not limited to the particular embodiments thereof illustrated and described herein, and I set forth its scope in my following claims.

I claim:

1. A vascular prosthetic implant comprising a tubular fabric body circumferentially integrally fashioned of sterilizable tissue-compatible synthetic multi-filament yarns having a fineness of the order of 70 denier and being compactly disposed in the fabric of the tubular body for according thereto a predetermined limited but tissue-growth-promoting porosity value in the range of about 16 to 30 in terms of cubic feet of air a minute per square foot of fabric at a pressure of 1.26 in. of water,

said tubular implant body having a normally open lumen within a uniform-diametered cylindrical interior wall defined by axially continguous and effectively continuous smooth fabric rings spanning between the inner bases of and held open by external circumferential micro-crimps of outward extent substantially less than the lumen radius and disposed in axially compacted randomly contiguous array for structurally affording to the implant in the absence of additive fabric stiffening treatment the capacity of self-maintenance in open lumen status under subjection to expectable use flexure and of self-restoration to such open status on release of temporarily constricting external pressure,

said tubular implant in said normal open form possessing high lateral flexibility and resilience and being elastically extensible and contractible axially.

2. A vascular prosthetic implant according to claim 1 fashioned as a single continuous tube.

3. A vascular prosthetic implant according to claim 1 fashioned in bifurcate form including a tubular main stem and angular legs branching integrally from one end thereof, the stem and legs being similarly fashioned with said inner-wall rings and said outer-wall axially compacted micro-crimps in continuous array from end to end of the implant as a whole, and the juncture of the stem and legs being integral and merging into a central crotch-closing fillet of the constituent fabric.

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