UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TRIVASCULAR, INC.
Petitioner

v.

SHAUN L. W. SAMUELS
Patent Owner

Case No. TBD

Patent 6,007,575

PETITION FOR *INTER PARTES* REVIEW

UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.1 *ET SEQ.*

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APPENDIX OF EXHIBITS

Exhibit Number	Exhibit Description	
1001	Samuels '575	U.S. Patent No. 6,007,575
1002	Samuels '851	U.S. Patent No. 5,423,851
1003	Rogers '024	U.S. Patent No. 5,534,024
1004	Lazarus '088	U.S. Patent No. 5,693,088
1005	Rhodes '117	U.S. Patent No. 5,665,117
1006	Lane '029	U.S. Patent No. 5,494,029
1007	Miller '767	U.S. Patent No. 3,991,767
1008	Todd '745	U.S. Patent No. 5,423,745
1009	Sisson '505	U.S. Patent No. 4,586,505
1010	Pigott '620	U.S. Patent No. 5,156,620
1011	Holman '537	U.S. Patent No. 5,871,537
1012	Samuels '575 USPTO prosecution file history [Prepared by Thomson Reuters]	
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1014	Excerpts from Merriam -Webster's Ninth New Collegiate Dictionary, 1986. [Ridge and Circumferential]	

I. The Petition

Petitioner, real party-in-interest TriVascular, Inc. hereby petitions the Patent Trial and Appeal Board (the "Board" or the "PTAB") of the United States Patent and Trademark Office ("PTO"), pursuant to 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.1 *et seq*., to institute an *inter partes* review, to find and cancel all the claims of U.S. Patent No. 6,007,575, entitled "Inflatable Intraluminal Stent and Method for Affixing Same within the Human Body", issued December 28, 1999 (serial no. 08/870,745, filed June 6, 1997) ("Samuels '575"), upon information and belief, owned by the named inventor Shaun L.W. Samuels ("Patent Owner"), as unpatentable. Samuels '575 is submitted herewith as Exhibit 1001. There is a reasonable likelihood that Petitioner will prevail with respect to at least one claim challenged in this petition.

II. Mandatory Notices

As set forth below and pursuant to 37 C.F.R. § 42.8(a)(1), the following mandatory notices are provided as part of this petition.

A. Real party-in-interest.

Pursuant to 37 C.F.R. § 42.8(b)(1) Petitioner, TriVascular, Inc. ("TriVascular"), a California corporation, 3910 Brickway Blvd., Santa Rosa

California, 95403, is the sole real party-in-interest.

B. Related matters (37 C.F.R. § 42.8(b)(2))

Other than as noted below, Petitioner is not aware of any other judicial or administrative matter that, potentially or actually, would affect, or be affected by, a decision in the proceeding herein. Samuels '575 is currently being asserted by Patent Owner against Petitioner in the U.S. District Court for the Northern District of California, *Dr. Shaun L.W. Samuels v. Trivascular, Inc.*, No. 3:13-cv-02261 (EMC), filed May 17, 2013.

C. Lead and Back-up Lead Counsel (37 C.F.R. §§ 42.8(b)(3) and 42.10(a)).

Petitioner designates the following individuals as its lead counsel and back-up lead counsel:

Lead Counsel	Back-up Lead Counsel
Daniel A. Scola, Jr.	Michael I. Chakansky
Reg. No. 29,855	Reg. No. 31,600
Hoffmann & Baron, LLP	Hoffmann & Baron, LLP
dscola@hbiplaw.com	mchakansky@hbiplaw.com
(973) 585-2003	(973) 585-2024

D. Service information (37 C.F.R. §42.8(b)(4)).

Service on Petitioner may be made electronically by using all the following three email addresses together in providing service: dscola@hbiplaw.com; mchakansky@hbiplaw.com; and ipr@hbiplaw.com. Service on Petitioner may be

made by Postal Mailing or Hand-delivery addressed to Lead and Back-up Lead Counsel at the following address, but electronic service above is requested:

Hoffmann & Baron, LLP
6 Campus Drive
Parsippany, New Jersey 07054

III. Payment of fees

Pursuant to 37 C.F.R. §§ 42.103 and 42.15(a), the undersigned authorizes the PTO to charge the $27,400 (Samuels '575 has 24 claims) filing fee for this Petition for *Inter Partes Review* to Deposit Account No. 08-2461. All 24 claims of the '575 Patent are being reviewed as part of this Petition. The undersigned further authorizes payment from and to the above referenced Deposit Account for any additional fees or refund that may be due in connection with the Petition.

IV. Additional Requirements for *Inter Partes* Review

A. Grounds for Standing (37 C.F.R. § 42.104(a)).

Petitioner hereby certifies that Samuels '575 is available for *inter partes* review and that Petitioner is not barred or estopped from requesting *inter partes* review challenging the claims of Samuels '575 on the grounds identified herein.

B. Identification of Challenge and Relief Requested (37 C.F.R. § 42.104(b) and 37 C.F.R. § 42.22(a)(1)).

The precise relief requested by Petitioner is that claims 1-24 (all the claims

of Samuels '575) are found unpatentable and cancelled from Samuels '575.

1. Claims for which Inter Partes Review is Requested (37 C.F.R. §42.104(b)(2))

Petitioner requests *inter partes* review of claims 1-24 of U.S. Patent No. 6,007,575 to Samuels ("Samuels '575").

2. Specific Statutory Grounds on which the Challenge is Based (37 C.F.R. §42.104(b)(2))

The specific statutory grounds for the challenge are as follows:

Ground	Reference(s)	Ground	Claims Challenged
1	Samuels '851	§102(b) and/or §103(a)	1-2, 6-15 and 18-24
2	Rogers '024	§102(e) and/or §103(a)	1-6, 11, 14-17 and 21
3	Samuels '851 and Rogers '024	§103(a)	1-24
4	Samuels '851 and Lazarus '088	§103(a)	1-2 and 4-24
5	Samuels '851 and Rhodes '117	§103(a)	1-2, 4-16 and 18-24
6	Samuels '851 and Lane '029 or Miller '767 or Todd '745 or Sisson	§103(a)	1-2, 6-15 and 18-24
7	Lazarus '088 and Miller '767 or Todd '745 or Sisson '505	§103(a)	1, 4-6, 9-11, 13-14, 16-17 and 19-21
8	Holman '537 and Pigott '620 and Lane '029	§103(a)	1-2, 4-8, 11, 13-18, 21

Petitioner contends that claims 1-24 of Samuels '575 are unpatentable under 35 U.S.C. §§102 and/or 103, with the following prior art references being cited in support of the challenge: U.S. Patent No. 5,423,851("Samuels '851"; Ex 1002); U.S. Patent No. 5,534,024 ("Rogers '024"; Ex 1003); U.S. Patent No. 5,693,088 ("Lazarus '088"; Ex 1004); U.S. Patent No. 5,665,117 ("Rhodes '117"; Ex 1005); U.S. Patent No. 5,494,029 ("Lane '029"; Ex 1006); U.S. Patent No. 3,991,767 ("Miller '767"; Ex 1007); U.S. Patent No. 5,423,745 ("Todd '745"; Ex 1008); U.S. Patent No. 4,586,505 ("Sisson '505"; Ex 1009); U.S. Patent No. 5,156,620 ("Pigott '620"; Ex 1010); and U.S. Patent No. 5,871,537 ("Holman '537"; Ex 1011). All the foregoing art qualify as prior art against Samuels '575 under 35 U.S.C. §§ 102 and/or 103.

The references set forth in the table below are U.S. patents which were filed prior to Samuels '575's filing date of June 6, 1997.

§102(e) Reference	Filing Date	Exhibit No.
Rogers '024	November 4, 1994	1003
Lazarus '088	June 7, 1995	1004
Rhodes '117	March 21, 1996	1005
Holman '537	February 13, 1996	1011

Thus, Rogers '024, Lazarus '088, Rhodes '117, and Holman '537 are each prior art to Samuels '575 under 35 U.S.C. §§ 102(e) and103(a), as are the U.S. patents below which issued more than one year prior to Samuels '575's filing date of June 6, 1997.

§102(b) Reference	Date of Issuance	Exhibit No.
Samuels '851	June 13, 1995	1002
Lane '029	February 27, 1996	1006
Miller '767	November 16, 1976	1007
Todd '745	June 13, 1995	1008
Sisson '505	May 6, 1986	1009
Pigott '620	October 20, 1991	1010

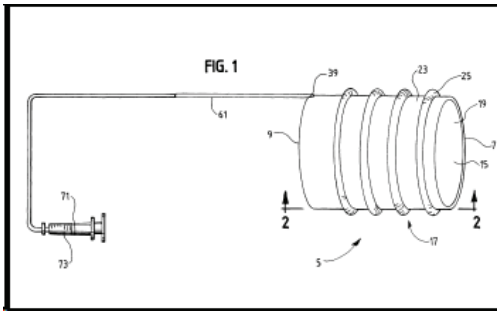
None of Rogers '024, Lazarus '088, Rhodes '117, Lane '029, Miller '767, Todd '745, Sisson '505, and Holman '537 was of record during prosecution of the application that issued as Samuels '575, with none of those references being relied upon in any rejection. The arguments made herein regarding any art mentioned in the prosecution history of Samuels '575 were not made during the prosecution of the patent application and those references of record are being applied in a different manner.

C. Claim Construction - Broadest Reasonable Interpretation ("BRI") (37 C.F.R. § 42.104(b)(3)).

A claim in an unexpired patent "shall be given its broadest reasonable construction in light of the specification of the patent in which it appears". 37 C.F.R. § 42.100(b). Nothing herein addresses the correct claim construction as given by the courts in a judicial litigation context. The words of the claim should be given their plain meaning unless inconsistent with the specification. *In re Zletz*, 893 F.2d 319, 321 (Fed. Cir. 1989).

1. Means plus function limitations

a. "means for injecting an inflation material into said cuff to inflate it", "means for inflating the cuff with inflation material in fluid communication with said inflation port" and "means for inflating the plurality of cuffs with inflation material"



Samuels '575, Figure 1.

"Referring back to FIG. 1, cuff 17 is inflated by way of an inflation syringe 71 with an inflation material 73. The inflation material could be a saline-based fluid or a material that contains a photo-activated or heat-activated hardening agent or any hardening agent that hardens over time." Samuels '575, col . 4, ll. 33-41.

"13. The inflatable intraluminal stent of claim 1 wherein the means for injecting an inflation material into said inflatable cuff to inflate it includes an inflation syringe and inflation tubing." Samuels '575, claim 13.

See also Samuels '575, col. 5, l. 62 - col. 6, l. 14. Thus the above-referenced "means for" clauses simply mean "inflation tubing connected to an inflation syringe filled with inflation material".

b. "means for securing an intraluminal medical device to the inner surfaces of the cuffs"

"[M]edical device may be secured to inner surface 19 of cuff 17 by way of biologically inert adhesives." Samuels '575, col. 3, ll. 39-41.

"A graft 92 is held by its end portions to the interior surfaces of stents 94, shown in an inflated condition, by biologically inert adhesive 95." Samuels '575, col. 5, ll. 29-34.

Thus "means for securing an intraluminal medical device to the inner surfaces of the cuffs" means a "biologically inert adhesive".

2. Claim terms particularly described in Samuels '575

a. "friction-enhancing outer surface"

"The stent features a cuff having an inflatable chamber and a friction-enhancing outer surface. The friction-enhancing outer surface engages the interior surface of the tubular structure without penetration when the inflatable cuff is in an inflated condition." Samuels '575, Abstract.

"The stent of the present invention features an inflatable cuff having an inner surface, an outer surface, and an inlet and an outlet with a lumen extending therebetween. The outer surface has a friction-enhancing face that engages the interior surface of the tubular structure, without penetrating it, when the inflatable cuff is deployed. If the initial placement of the stent within the tubular structure is not optimal, it may be deflated, repositioned to the optimal position and reinflated so as to again be affixed to the tubular walls via its outer surface. The tissue of the walls is not damaged or harmed by its

> exposure to the friction-enhancing face of the stent outer surface." Samuels '575, col. 2, ll. 33-44.
>
> "As shown in FIG. 1, outer surface 23 features a number of inflatable ridges 25 disposed about its circumference. While inflatable ridges are shown in the FIGS., any friction- enhancing outer surface, that would secure the inflated stent to the interior wall of a tubular structure without penetrating it, could be used. For example, the surface could feature nubs, bumps, indentations, etc." Samuels '575, col. 3, ll. 34-38.
>
> "As an example of an alternative friction-enhancing surface, another embodiment of the stent of the invention is shown in FIG. 3. As illustrated in FIG. 3, the outer surface 30 of the cuff is made coarse by a combination of raised portions 31 and lowered portions 33. These surface features allow the inflated stent to grip the interior walls of a tubular structure with a force that is sufficient to prevent its migration." Samuels '575, col. 3, ll. 60-67.

Thus a "friction-enhancing outer surface" means the surface features of the outer surface of an inflatable cuff, such as inflatable ridges, nubs, bumps and indentations, such that when the inflatable cuff is deployed, such surface features engage or secure the inflated stent to the interior wall of a tubular structure without penetrating it or harming or damaging the tissue of the walls of the tubular structure.

b. "circumferential ridge disposed about the inflatable cuff"

> "As shown in FIG. 1, outer surface 23 features a number of inflatable ridges 25 disposed about its circumference. While inflatable ridges are shown in the FIGS., any friction-enhancing outer surface, that would secure the inflated stent to the interior wall of a tubular structure without penetrating it, could be used. For example, the surface could feature nubs, bumps, indentations, etc." Samuels '575, col. 3, ll. 34-38.
>
> "As illustrated in FIG. 2, circumferential ridges 25 are in fluid communication with the inflatable chamber 27 of cuff 17. Spot welds 28, positioned incrementally about the circumference and parallel with the longitudinal axis of cuff 17, prevent distention of the flat portions of the outer surface 23 of cuff 17." Samuels '575, col. 3, ll. 54-59.

The ordinary and customary meaning of the terms "circumferential" and "ridge" may be found in Merriam -Webster's Ninth New Collegiate Dictionary, 1986 (Ex 1014). Namely: (1) "Circumference. 1: the perimeter of a circle ... 2: the external boundary or surface of a figure or object . . . Circumferential . . . adj"; and (2) "Ridge. 1: an elevated body part (as along the backbone)". Thus the broadest reasonable interpretation of "circumferential ridge disposed about the inflatable cuff" means "an elevated part of the outer surface disposed about the inflatable cuff".

3. Claim terms without support must also be given BRI

   a. "when said cuff is in a fully inflated condition"; "when the cuff is fully inflated"

The term "fully inflated" has no support in Samuels '575. It was added in Amendment A (Ex 1013, pp.28,29) which also did not identify any support therefor. Samuels '851 had been cited against all claims of the Samuels '575 application under 35 U.S.C. § 102. (Ex 1013, pp. 2-3; Office Action, pp. 3-4.) "In response, independent claims 1 and 16 have been amended to recite that the friction-enhancing outer surface of the cuff engages the interior tubular structure without penetration when the cuff is fully inflated." (Ex 1013, p.30; Amendment B, p.4). See further discussion of prosecution of Samuels '575 below. Thus the claim terms "when said [the] cuff is in a fully inflated condition" and "when the cuff is fully inflated" each means, when given the required broadest reasonable interpretation, "when the cuff is inflated to the extent that the cuff is affixed to the lumen of the tubular structure but not inflated to the extent that it penetrates the tubular structure." All other terms of all challenged claims are presumed to take on their ordinary and customary meanings in light of their broadest reasonable interpretation.

V. Summary of the Samuels '575 Patent (Ex 1001)

A. Background of Samuels '575.

Samuels '575 is directed to an inflatable intraluminal stent for treating conditions, such as aneurisms. The stent is formed from an inflatable cuff. The inflatable cuff has a valve which allows the cuff to be inflated with inflation

material. The inflatable cuff also has inflatable "friction-enhancing" surface features on its outer surface which inflate with the cuff when the cuff is inflated to allow the cuff to engage the inner surface of a tubular structure, such as blood vessel or other body lumen, using friction. The outer surface of the inflatable cuff is thus designed to be "friction-enhancing," and has surface features, such as ridges, nubs, bumps and raised and lowered portions, for that purpose. A surface feature which is inflated when the cuff is inflated allows the stent to become securely engaged to the tubular structure so that the stent does not migrate within the tubular structure. In particular, the inflatable cuff, which may have an additional medical device (such as a graft) glued to its inner surface, can be reportedly positioned and repositioned within the tubular structure without penetrating and damaging the tubular structure.

B. Prosecution History of Samuels '575.

The Samuels '575 prosecution history as obtained by Petitioner from Thomson Reuters is found at Ex 1012. A shortened version with the documents referred to below can be found in Ex 1013. The application which issued as the Samuels '575 patent was filed with twenty-nine claims. (*See*, Exhibit 1013, pp.3-7.) In response to a restriction/election requirement (Ex 1013, pp. 11-13), the Applicant elected to prosecute claims 1, 3-11, 15, 16, and 18-22 (Ex 1013, pp. 16-17; Amendment A, pp. 1-2).

The Examiner rejected claims 1, 3-4, 8-9, 11, 15-16, 18 and 22 under 35 U.S.C. §102(b) as being anticipated by Samuels '851; claims 1, 3-4, 8, 15-16, and 18 under 35 U.S.C. §102(b) as being anticipated by Lane '029; and claims 1, 3-10, 16, and 18-21 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,554,180 to Turk ("Turk '180"). (Office Action, pp. 1-3; Ex 1013, pp. 20-23.) Applicant did not traverse or object to the rejections but rather amended claims 1, 3, 4, 16, and 18. *See* Amendment B (Ex 1013, pp. 27-33). In particular, independent claims 1 and 16 were amended, in part, to ad that the cuff is "fully" inflated. For example, during prosecution claim 16 was amended to provide:

> "b) said friction-enhancing outer surface affixing the cuff within the lumen of the tubular structure without penetration of the tubular structure when the cuff is <u>fully</u> inflated <u>so that movement of the cuff in a longitudinal direction with respect to the tubular structure is prevented</u>" Amendment B, p. 3 (Ex 1013, p. 29).

Claim 1 was amended to add "fully" inflated in a similar manner. *See* Amendment B, p. 2 (Ex 1013, p. 28).

The term "fully inflated," which does not appear in the original claims, was thus added by the Applicant during prosecution. No reference was made to where the term "fully inflated" is supported by the specification– probably because it is nowhere to be found and is thus not supported by the Samuels '575 specification. Nevertheless, Applicant sought to overcome the Samuels '851 § 102 rejection by

representing that claims 1 and 16 have "been amended to recite that the friction-enhancing outer surface of the cuff engages the interior of the tubular structure without penetration when the cuff is fully inflated." Amendment B, p.4 (Ex 1013, p. 30).

Applicant also amended claims 3 and 4 in his attempt to overcome the Samuels '851 § 102 rejection. Claim 3 was amended to change "inflatable protrusion(s)" to "inflatable protrusion(s) without rigid components", a negative limitation presumably added to indicate absence of barbs. Claim 4 was amended to change the recitation "at least one circumferential ridge disposed about said inflatable cuff" to "at least one circumferential ridge continuously disposed about said inflatable cuff." Amendment B, p. 3 (Ex 1013, p. 29). Applicant did not refute that protrusions 12 and 18 of Samuels '851 constitute a circumferential ridge as was stated by the Examiner (Office Action, pp.3; Ex 1013, pp.22). Instead, he accepted that Samuels '851 disclosed them and merely argued that "the protrusions 12 and 18 of the Samuels '851 patent do not form a continuous circumferential ridge." Amendment B, p.5 (Ex 1013, p.31).

Subsequent to a telephone interview with the Examiner, the Applicant cancelled claims 1, 3, 4, 16, 18, and 30, added new claims 31 and 32, and amended claims 5, 6, 8-11, 15, 19, 21, and 22 to change their dependencies. Amendment C, pp.1-4 (Ex 1013, pp.39-44). Applicant characterized claims 1 and 16 as "rewritten

as claims 31 and 32, respectively, to incorporate the limitations of claims 3 and 4 (with claims 3 and 4 in the form originally presented, that is, without the changes of previously filed Amendment 'B')." (Ex 1013, p.42.) New claims 31 and 32 thus omitted limitations which Applicant had previously added to overcome the cited prior art.

In an Examiner's Amendment (*see* Ex 1013, pp. 46-48), previously withdrawn independent claim 26 was resurrected (as claim 23, Ex 1013, p. 47) and amended to provide: "said friction-enhancing outer surfaces <u>featuring inflatable protrusion(s) including at least one circumferential ridge disposed about the inflatable cuff and</u> affixing …". (Ex 1013, p.47) Thus the phrase "<u>continuous</u> circumferential ridge", which was used to overcome Samuels '851, is not present in any of the Samuels '575 patent claims for which *inter partes* review is requested.

VI. Each Ground Provides More than a Reasonable Likelihood That Each Claim of Samuels '575 Is Unpatentable

Provided below are detailed discussions of each ground for claim invalidation, a collection of relevant figures from the prior art, and claims charts for Grounds 1 - 3 and for Grounds 4 - 8. Where thought useful, claim phrase identifiers appear in brackets, *e.g.* "[1a-1]" in all the claims charts, only to assist in discussion of the prior art. Petitioner notes that all the prior art cited herein may be

combined with each other, and should not be limited by the way Petitioner has organized the grounds and prior art citations herein. All possible combinations were not discussed due to space limitations and the absence of a particular description in Charts I and II or a check mark in Chart III does not mean that the references are not relevant to any invalidity arguments. Thus absence of an entry in any claims chart is not an admission that the particular prior art does not disclose and/or possess that element or claim phrase identifier. Petitioner expressly reserves the right to present arguments, if applicable, that the particular prior art does disclose and possess same.

A. Detailed Claim Challenges by Ground.

Ground 1: §102(b) and/or §103(a) Samuels '851 [Claims 1-2, 6-15, 18-24]

Samuels '851 includes each of the elements in claims 1-2, 6-15, 18 and 24 and thus anticipates these claims and/or renders them obvious under 35 U.S.C. §§ 102 and 103. Samuels '851 includes each and every element of these claims and thus anticipates them. Samuels '851 explicitly discloses (*see* references to FIG. 3 at Col. 3, l. 56- col. 4, l. 10) that the outer surface of its cuff, when inflated, engages the tubular structure in the body without causing damage to the surrounding tissue. That is, the Samuels '851 device can be positioned and through inflation of the cuff engage the walls of the tubular structure keeping it at that location without using the barbs and thus without penetration. Moreover, the

Samuels ‘851 device can be deflated and moved to another position and then re-inflated so as to once again engage the walls.

> “Referring to FIG. **3**, a sectional view of a partially inflated inflatable cuff **10** is illustrated showing the engagement of its outer surface **14** with the structure's wall when the barbs **18** are inside the recesses. FIG. **3** highlights a unique feature of the present invention which is its capability of being optimally positioned within the tubular structure in the body without causing damage to the surrounding tissue. Specifically, when the balloon cuff **10** is at lower levels of inflation and after it has been inserted into the body by catheterization, the outer surface **14** holds the cuff **10** in place against the wall **30** so that it can be determined whether the positioning of the medical device and the cuff **10** is optimal. . . . [I]f the position is not optimal, then the cuff **10** can be deflated and moved to the optimal position without harming or damaging the surrounding tissue.” Samuels ‘851, col. 3, l 57 - col. 4, l 10, Ex 1002.

See also, Claims Chart I, [1a-4]. Thus, Samuels ‘851 provides for holding a medical device in position relative to the wall of the tubular structure without damage to the wall by inflating the cuff as needed to do so; exactly what Samuels ‘575 purports to accomplish and claim.

Importantly, even at higher levels of inflation Samuels ‘851 makes Samuels ‘575 obvious. Simply put, by removing the barbs (18) from Samuels ’851 one immediately arrives at Samuels ‘575 as recited in the claims. Additionally, the

claim language "without penetration" is purely functional and should be given no weight, particularly because '851 allows for the device to operate without penetrating. *See* Samuels '851, col. 2, ll. 2-6 and col 3, ll. 64-68. Furthermore, it was common knowledge at the time of the invention that problems existed when using barbs and the like in intraluminal devices and the trend was to make these inflatable intraluminal devices using non-vessel piercing methods. *See, e.g.,* several of the other references, such as Lazarus '088 which is contemporaneous in time and which explicitly teaches preventing migration without penetrating a vessel. Thus a person of ordinary skill in the art ("POSA") would be motivated to to remove the barbs from the stent of Samuels '851, thereby arriving at the device of the Samuels '575 recited claims.

As the Supreme Court stated in *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 406, 417 (2007), in evaluating obviousness, "if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. . . a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions". Moreover, "[u]nder the correct analysis, any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements 1 in the manner

claimed." *Id.* at 420. The step in removing the barbs is not inventive because to do so would merely be following the obvious teachings of both common knowledge and other prior art references.

Ground 2: §102(e) and/or 103(a) Rogers '024 [Claims 1-6, 11, 14-17 and 21]

Rogers '024 includes each of the elements in claims 1-6, 11, 14-17 and 21 and thus anticipates these claims and/or renders them obvious under 35 U.S.C. §§ 102 and 103. Rogers provides his fluid-filled chamber for the exact purpose and to solve the same problem as Samuels '575, namely to treat aneurysms without penetrating the vessel. Rogers '024 has inflatable portions at each end which fluidly communicate with inflatable protrusions on the surface. These inflatable protrusions run nearly the full length of the tubular graft and are positioned about the circumference of the tubular device for the purpose of maintaining the device in place. Because the protrusions are positioned all the way around the circumference, as well as nearly the full length of the device, they would be expected to provide a friction-enhancing function without penetration of the vessel. *See also* Claims Chart I, [1a-4]. In fact, the cylinders (30) of Rogers '024 provide more surface contact than those shown in Samuels '575 and a POSA would expect such a configuration to be successful at fulfilling the fixation of the device in the vessel for its intended purpose. Importantly, Rogers '024 does not disclose nor require the use of barbs or any other device other than the disclosed inflatable outer

surfaces in order for its stenting graft to function as intended in providing for the flow of blood through the stenting graft "at the site of implementation". *See* Rogers '024, col. 3, ll 18-34. Thus, Rogers '024 anticipates or in the alternative renders the Samuels '575 claims obvious.

Ground 3: §103(a) Samuels '851 and Rogers '024 [Claims 1-24]

Claims 1-24 are obvious in light of the combination of Samuels '851 and Rogers '024 under 35 U.S.C. § 103(a). Rogers '024 discloses that inflatable protrusions in the form of cylinders positioned both circumferentially and longitudinally on the surface of the inflatable cuff portions on each end to keep the device in place to serve its intended purpose of treating the aneurysm. A POSA only need look at Rogers '024 to see that barbs are not necessary and simply remove them from Samuels '851 to arrive at these claims. In so doing, removing of the barbs cannot be said to be inventive. Both the motivation to do so and the likelihood of success are overwhelmingly demonstrated by such a combination.

Ground 4: §103(a) Samuels '851 and Lazarus '088 [Claims 1-2 and 4-24]

Claims 1-2 and 4-24 are obvious in light of the combination of Samuels '851 and Lazarus '088 under 35 U.S.C. § 103(a). Lazarus '088 provides an inflatable intraluminal graft "without the use of barbs or hooks." *See* Abstract. Lazarus '088 constructs his inflatable portions using porous materials which promote ingrowth to keep the graft in position without penetrating. *Id.* A POSA looking to

eliminate barbs need only look to Lazarus '088 for a clear teaching that barbs can and should be eliminated. Merely eliminating the barbs from Samuels '575 cannot be said to be inventive when the prior art provides ample teaching and direction to do so.

Ground 5: §103(a) Samuels '851 and Rhodes '117 [Claims 1-2, 4-16, and 18-24]

Claims 1-2, 4-16, and 18-24 are obvious in light of the combination of Samuels '851 and Rhodes '117 under 35 U.S.C. § 103(a). Rhodes '117 established that an inflatable PTFE (Teflon®) intraluminal graft (filled with hardening polymer) can be kept in place without penetrating the vessel wall. Rhodes '117 used inflatable cuffs to help secure the graft in place and although he mentions barbs, he also expressly teaches that such projections on a stent need not puncture the vessel wall. "[T]his action causes the projections to tightly engage (and not necessarily penetrate) the interior of the wall of the vessel…to fixedly secure the prosthesis in place against migration." Col. 8, ll. 23-27. Moreover, the "outer balloon means", *i.e.*, expandable circumferential support structures of Rhodes '117 (*see* col.3, ll. 27-30) aids in both positioning and creating a friction enhancing surface on the device. A POSA would either look to Rhodes '117 for clear direction about leaving out the barbs in Samuels '851 or modifying Samuels '851 that its barbs do not penetrate, thereby readily arriving at the Samuels '575 recited claims.

Ground 6: §103(a) Samuels '851 and Lane '029 or Miller '767 or Todd '745 or Sisson '505 [Claims 1-2, 6-15, and 18-24]

Claims 1-2, 6-15 and 18-24 are obvious in light of combinations of Samuels '851 with one or more of Lane '029, or Miller '767, or Todd '745, or Sisson '505 under 35 U.S.C. § 103(a). Each of Lane '029, Miller '767, Todd '745 and Sisson '505 provides friction enhancing surfaces for preventing migration. In Lane '029 this takes the form of bumps, ridges or raised texture as discussed above. *See* Figs. 4-6 and Col. 5, ll. 17-30. For each of Miller '767 and Sisson '505, the friction enhancing surfaces are inflatable circumferentially placed structures. For Todd '745, the inflatable balloon protuberances on its surface are friction- enhancing. *See* Figs. 5-9. Given the basic structure of Samuels '851, it would be an obvious modification to take the friction-enhancing features of any of these secondary references and modify Samuels '851 while maintaining its basic intent and purpose. Clearly the teachings of these references when combined not only provide various non-penetrating aspects of creating friction-enhancing surfaces but disclose the same inflatable ridges circumferentially positioned about the devices. For these reason, combinations of Samuels '851 and the above references render the above-recited claims obvious.

Ground 7: §103(a) Lazarus '088 and Miller '767 or Todd '745 or Sisson '505 [Claims 1, 4-6, 9-11, 13-14, 16-17, and 19-21]

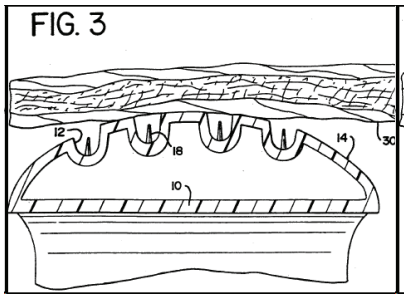
Claims 1, 4-6, 9-11, 13-14, 16-17 and 19-21 are obvious in light of combinations of Lazarus '088 with one or more of Miller '767, or Todd '745, or Sisson '505 renders claims obvious under 35 U.S.C. § 103(a). As mentioned in Ground 4, the main focus of Lazarus '088 is to provide an inflatable intraluminal graft "without the use of barbs or hooks." *See* Abstract. Lazarus '088 constructs his inflatable portions using porous materials which promote ingrowth in order keep the graft in its proper place without barbs or other penetrating devices. *See* Abstract. As stated in Ground 6, each of Miller '767, Todd '745 and Sisson '505 provides inflatable proturberances which prevent migration. A POSA looking to make an intraluminal device for treating aneurysms would look to Lazarus '088 and modify it with the teachings of any one or more of these references to arrive at the Samuels '575 recited claims. A review of the claim charts provides a clear blueprint for such obvious modification.

Ground 8: §103(a) Holman '537 and Pigott '620 and Lane '029 [Claims 1-2, 4-8, 11, 13-17, 21]

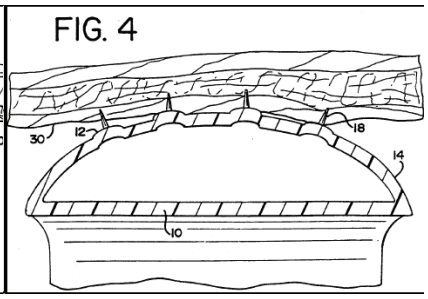
Claims 1-2, 4-8, 11, 13-17 and 21 are obvious in light of the combination of Holman '537 and Pigott '620 and Lane '029 under 35 U.S.C. § 103(a). Holman '537 shows an intraluminal device having inflatable cuffs. To modify Holman to include a valve would be obvious to a POSA in view of Pigott '620. Moreover, Lane '029 provides clear teachings with respect to friction-enhancing features. *See* Lane '029, Figs. 4-6, below also, in particular the surface of the inflatable

chambers, elements 12, 42 and 44 therein. To further modify one or more inflatable cuffs to include friction- enhancing features are thus clearly suggested by Lane '029. Such a combination of features would be obvious to a POSA because each of the valve and the friction-enhancing features would leap to the mind of any POSA looking to use them for their well-known purposes. Thus, Holman '537 when used in combination with the teachings of Pigott '620 and Lane '029 clearly suggest the recited claims. Modifying Holman '537 in such a way is simply combining well-known parts in similar devices to serve the intended function.

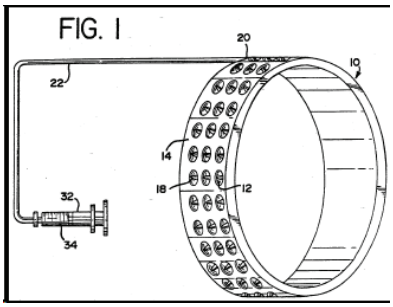
B. Some relevant Figures from the Prior Art Cited in Grounds 1-8



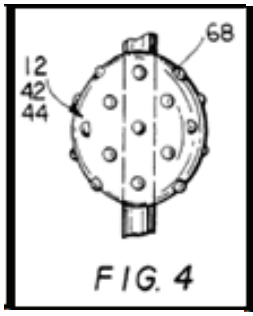
Samuels '851



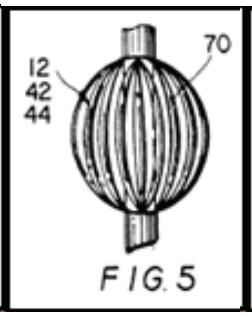
Samuels '851



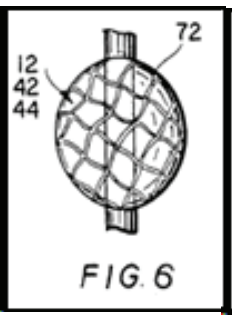
Samuels '851



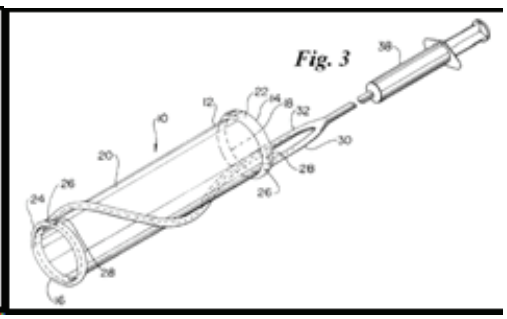
Lane '029



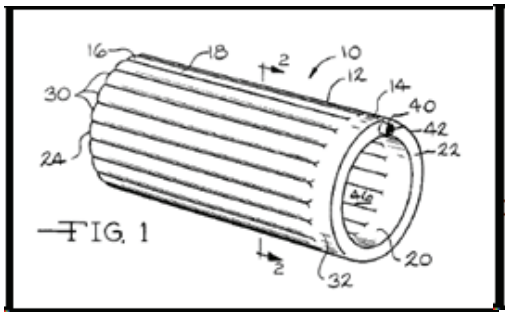
Lane '029



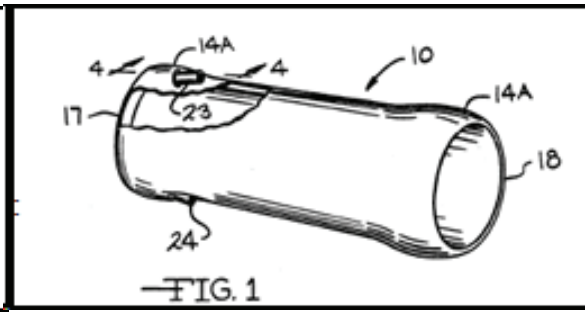
Lane '029



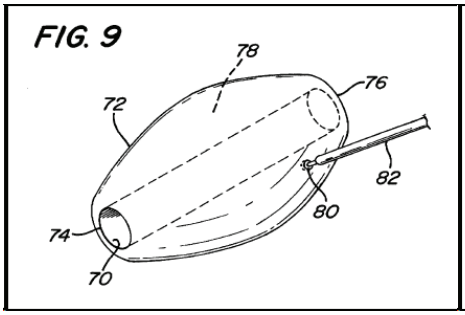
Holman '537



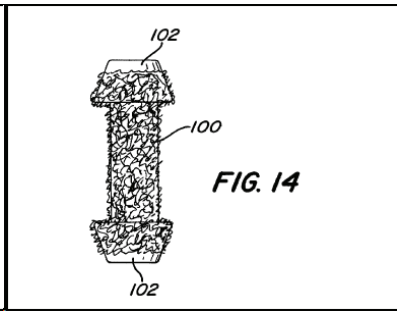
Rogers ‘024



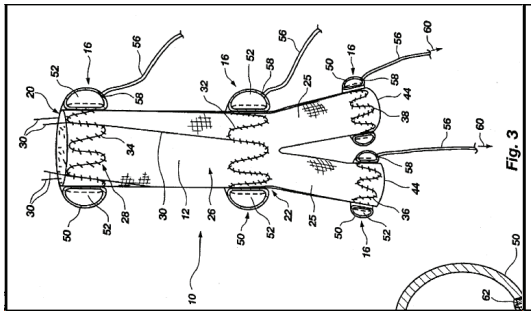
Pigott ‘620



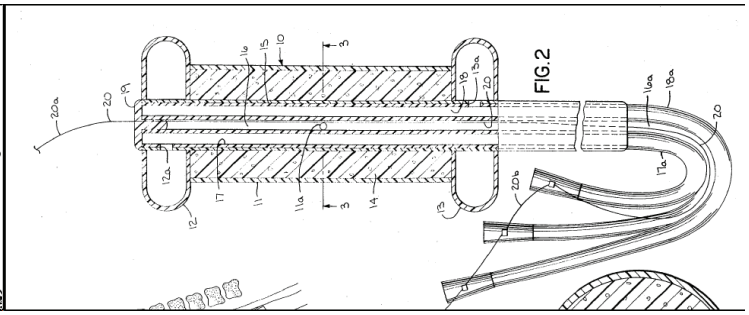
Rhodes ‘117



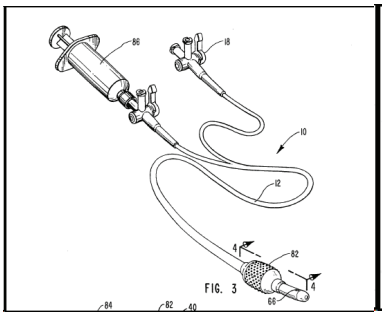
Rhodes ‘117



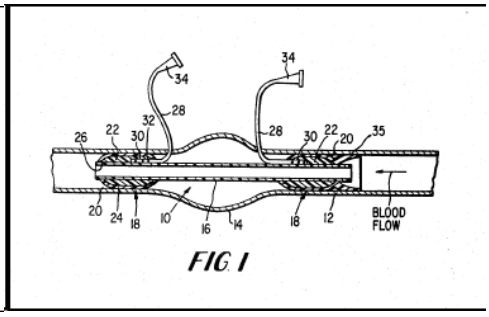
Lazarus ‘088



Sisson ‘505



Todd ‘745



Miller ‘767

C. The Claims Charts.

1. Claims Chart I for Grounds 1, 2 and 3.

Samuels '575 Has Claims 1-24	**Ground 1: §102(b) and/or §103(a) Samuels '851** [Claims 1-2, 6-15, 18-24] **Ground 2: §102(e) and/or §103(a) Rogers '024** [Claims 1-6, 11, 14-17 and 21] **Ground 3: §103(a) Samuels '851 and Rogers '024** [Claims 1-24]
[1] 1. An inflatable intraluminal stent adapted to be secured to the interior of a tubular structure within the human body comprising:	**Samuels '851:** "apparatus for affixing an endoluminal device to the walls of tubular structures within the body" (Abstract; Col. 1, ll 10-13, Col. 1, l 67 to Col. 2, l 1; *see also* Col. 2, ll 10-11, 36-37); "FIG. **1** is a pre-deployment perspective view of an apparatus for affixing an endoluminal medical device within the tubular structures of the body before the cuff has been inflated…." (Col. 2, ll 9-12; FIG. 1; (Col. 2, ll 35-39); "FIG. **2** is a post-deployment perspective view of an apparatus….." (Col. 2, ll 13-14; FIG. 2); "human body" (Col. 4, ll 40-41); "an inflatable balloon cuff" (Col. 2, ll 40-42); "The cuff **10** is inflated and deflated by means of valve **20** (FIGS. **5** and **6**)" (Col. 2, ll 65-66); "inner surface of an inflatable balloon cuff **10**" (Col. 2, ll 40-41); "inflatable cuff **10** and its outer surface **14**" (Col. 2, ll 48-49); etc. **Rogers '024:** "An intraluminal stenting graft for implantation in a blood vessel" (Abstract; *see also* Col. 2, ll 47, 51, 56, and 63; etc.)
[1a-1] a) an inflatable and deflatable cuff of generally hollow cylindrical continuation having a collapsible lumen, an inner surface, an inlet, an outlet and	**Samuels '851:** "An inflatable balloon cuff" (Col. 2, ll 40-42); "The cuff **10** is inflated and deflated by means of a valve **20** (FIGS. **5** and **6**)" (Col. 2, ll 65-66); "inner surface of an inflatable balloon cuff **10**" (Col. 2, ll 40-41); "inflatable cuff **10** and its outer surface **14**" (Col. 2, ll 48-49); etc.. **Rogers '024:** "….intraluminal stenting graft includes a collapsible tube member having a first end and a second end. An outer layer and an inner layer extend between the ends." (Abstract); *see also* Col. 1, ll 4-10, 23-24 and 66-67; Col. 3, ll 19-20; "As shown in FIGS. **1**, **2**, and **4**, the outer layer **18** is joined to the inner layer **20** to form a plurality of cylinders

	30…the tube member **12** can include a radially extending chamber **32** that is in communication with the plurality of cylinders 30." (Col. 2, ll 33-39; FIG. 1)
[1a-2] a friction enhancing outer surface, said friction-enhancing outer surface	**Samuels '851:** "an inflatable balloon cuff **10** which includes a plurality of reinforced recesses **12** radially arrayed around its outer surface **14**." (Col. 2, ll 40-42); "As more precisely shown in FIGS. **3** …, the recesses **12** are dome-shaped when the cuff is fully inflated." (Col. 2, ll 57-59; FIG. 3) **Rogers '024:** Cylinder(s) 30; outer layer 18 (*See, e.g.*, Col. 2, ll 33-37; FIG. 1)
[1a-3] featuring inflatable protrusion(s) including at least one circumferential ridge disposed about the inflatable cuff,	**Samuels '851:** "cuff **10** which includes a plurality of reinforced recesses **12** radially arrayed around its outer surface **14**" (Col. 2, ll 40-42); "When the cuff **10** is fully inflated, the recesses **12** pop out …." (Col. 2, ll 62-63) **Rogers '024:** cylinder(s) 30 (*See* Col. 2, ll 33-37; FIG. 1)
[1a-4] said friction-enhancing outer surface engaging the interior of the tubular structure without penetration to prevent the cuff from moving in a longitudinal direction with respect to the tubular structure when said cuff is in a fully inflated condition;	**Samuels '851:** "**Referring to FIG. 3**, a sectional view of a partially inflated inflatable cuff **10** is illustrated **showing the engagement of its outer surface 14 with the structure's wall when the barbs 18 are inside the recesses. FIG. 3 highlights a unique feature of the present invention which is its capability of being optimally positioned within the tubular structure in the body without causing damage to the surrounding tissue.** Specifically, when the balloon cuff **10** is at lower levels of inflation and after it has been inserted into the body by catheterization, the outer surface **14** holds the cuff **10** in place against the wall **30** so that it can be determined whether the positioning of the medical device and the cuff **10** is optimal. If the position is found to be optimal, then the cuff **10** is fully inflated so that the barbs **18** rigidly engage with the wall **30** to permanently hold the medical device in place. On the other hand, if the position is not optimal, then the cuff **10** can be deflated and moved to the optimal position without harming or damaging the

	surrounding tissue." (Col. 3, l 57 - col. 4, l 10 (emphasis supplied)); FIG. 3 **Rogers '024**: "….plurality of cylinders 30…cooperate to maintain the tube member 12 in a stable, expanded condition for implantation in a blood vessel." (Col. 3, ll 7-10); "…the fluid causes the collapsed tube member 12 to expand for implantation in a blood vessel" (Col. 2, ll 45-48); "The stenting graft **10** allows blood flow… **at the site of implantation**…." (Col. 3, ll 32-33) (emphasis added); "…intraluminal stenting graft for implantation…" (claim 1)
[1b] b) means for injecting an inflation material into said cuff to inflate it; and	**Samuels '851:** "Referring back to FIG. **1**, the cuff **10** is inflated by means of an inflation syringe **32**…" (Col. 4, ll 10-11); "inflation tubing **22**" (Col 3, ll 2; *see also* col. 3 ll 20-21) **Rogers '024:** "The fluid can be introduced into the tube member **12** … by a fluid conduit **44**." (Col. 2, ll 53-54; FIGS. 3, 5, 6)
[1c] c) a valve integral with the inflatable cuff for permitting entry of the inflation material from the means for injecting and thereafter sealing said cuff to prevent deflation.	**Samuels '851:** "The cuff **10** is inflated and deflated by means of valve **20** (FIGS. **5** and **6**) which is integral with a side of cuff **10**. Preferably, valve **20** is a duck bill valve. Duck bill valve **20** is comprised of opposing leaflets **21** of a non-elastomeric, biologically inert material and is used in conjunction with inflation tubing **22**. Tubing **22** is inserted into the valve **20** to separate the opposing leaflets **21** of the valve **20** when the cuff **10** is to be inflated or deflated. After the cuff **10** has been fully inflated, the tubing **22** is removed and the opposing leaflets **21** close to seal the inflated cuff **10**. Inflation material **34** is used…." (Col. 2, l 65 - Col. 3, l 8; FIGS. 1, 2, 7) **Rogers '024**: "… a one-way valve **42**, such as a check valve, can be positioned in the opening **40**. The valve **42** allows for the introduction of the fluid from the tube member **12**. The valve prevents the escape of the fluid from the tube member **12** after introduction into the tube member." (Col. 2, ll 48-51)
[2] 2. The inflatable intraluminal stent of	**Samuels '851**: "inflatable balloon cuff **10** which includes a plurality of reinforced recesses **12** radially arrayed around its outer surface **14**" (Col. 2, ll 40-42); "As more precisely

claim 1 wherein the friction-enhancing outer surface is a coarse surface.	shown in FIGS. 3 … the recesses 12 are dome-shaped when the cuff is fully inflated." (Col. 2, ll 57-59; FIG. 3) **Rogers '024**: "plurality of cylinders **30**" (Col. 2, l 34, *etc.*), FIG. 1 (showing indentations)
[3] 3. The inflatable intraluminal stent of claim 1 further comprising a plurality of spot welds between the inner surface and the friction-enhancing outer surface of the inflatable cuff in staggered relationship with the inflatable protrusion(s) to limit distention between the inner surface and the friction-enhancing outer surface.	**Rogers '024:** "As shown in FIGS. **1**, **2**, and **4**, the outer layer **18** is joined to the inner layer **20** to form a plurality of cylinders 30 that extend longitudinally between the first end **14** and the second end **16**." (Col. 2, ll 33-37; FIGS. 1, 2, and 4)
[4] 4. The inflatable intraluminal stent of claim 1 wherein the friction-enhancing outer surface is constructed of a material that promotes tissue ingrowth.	**Rogers '024:** "outer layer **18**…polytetrafluoroethylene" (Col. 2, ll 55-58)
[5] 5. The inflatable intraluminal stent of claim 4 wherein the material that	**Rogers '024:** "Referring to FIG. **2**, the outer layer **18** and the inner layer **20** are composed of a polymer material that is biocompatible. An example of such a material is polytetrafluoroethylene." (Col. 2, ll 55-58)

promotes tissue ingrowth is TEFLON.	[Teflon® is a trademark for polytetrafluoroethylene.]
[6] 6. The inflatable intraluminal stent of claim 1 wherein the inflatable cuff is composed of a polymeric plastic which is biologically inert.	**Samuels '851:** "…. the inflatable cuff **10** and its outer surface **14** are preferably composed of a minimally distensible and slightly elastomeric polymeric plastic which is biologically inert." (Col. 2, ll 47-51) **Rogers '024:** "Referring to FIG. **2**, the outer layer **18** and the inner layer **20** are comprised of a polymer material that is biocompatible." (Col. 2, ll 55-57); "inner and outer layers are comprised of a polymer material" (Col. 4, ll 58-59, Claim 5)
[7] 7. The inflatable intraluminal stent of claim 1 wherein the inflation material includes a hardening agent.	**Samuels '851:** "….inflation material **34** which is preferably a silicone-based liquid when injected into the cuff which hardens over time. After the inflation material **34** hardens . . . ." (Col. 4, ll 11-14)
[8] 8. The inflatable intraluminal stent of claim 1 wherein the valve is a mitre valve.	**Samuels '851:** "duck bill valve" (Col. 2, ll 26-28); "Preferably, valve **20** is a duck bill valve." (Col. 2, l 67) ["a 'duck bill' or 'mitre' [*sic* - "mitral"] valve" (**Samuels '575**, col. 4, ll 11-12.)]
[9] 9. The inflatable intraluminal stent of claim 1 wherein the valve is of a breakaway design to permit separation from the means for injecting.	**Samuels '851:** "pullaway detachable valve….When a pullaway valve is used, the cuff **10** is inflated and deflated at low pressure to confirm its position and then is fully inflated at a higher pressure. After the inflation material **34** inside the cuff is slightly hardened, the operator of the device pulls on the inflation tubing to break connection with the cuff where the lumen is thinnest." (Col. 3, ll 15-23);
[10] 10. The inflatable intraluminal stent of claim 1 further comprising means	**Samuels '851:** "The first step in using the present invention is to secure the medical device to the inflatable cuff **10** by means of biologically inert adhesives...." (Col. 3, ll 43-46)

for securing an intraluminal medical device to the inner surface of the inflatable cuff.	
[11] 11. The inflatable intraluminal stent of claim 10 wherein the intraluminal medical device is a graft for repairing aneurysms.	**Samuels '851:** "apparatus for affixing an endoluminal device to the walls of tubular structures within the body. Examples of such structures ….aneurysms…." (Col. 1, ll. 8-17); *see also* (Col. 3, ll 24-32); **Rogers '024:** "….an intraluminal stenting graft…. Intraluminal stenting grafts are implanted in a blood vessel to repair, for example, aortic aneurysms." (Col. 1, ll 5-15)
[12] 12. The inflatable intraluminal stent of claim 10 wherein the intraluminal medical device is a vena cava filter.	**Samuels '851:** "A non-exhaustive list of examples of applications of the present invention include: placing filters in the inferior vena cava . . . . A single cuff is used to secure a vena cava filter to a vessel wall." (Col. 3, ll 26-33)
[13] 13. The inflatable intraluminal stent of claim 1 wherein the means for injecting an inflation material into said inflatable cuff to inflate it includes an inflation syringe and inflation tubing.	**Samuels '851:** "Referring back to FIG. **1**, the cuff **10** is inflated by means of an inflation syringe **32** with an inflation material **34** ….. Typically, the inflation syringe **32** is mounted in a screw-feed pressure generating device provided with a manometer…." (Col. 4, ll 10-19); "inflation tubing" (Col 3, ll 20-21) **Rogers '024:** "The fluid can be introduced into the tube member **12** through the valve **42** by a fluid conduit **44**." (Col. 2, ll 53-54)
[14] 14. An apparatus for disposition within the lumen of a tubular structure within the human body comprising:	**Samuels '851:** "apparatus for affixing an endoluminal device to the walls of tubular structures within the body" (Abstract; Col. 1, ll 10-13, Col. 1, l 67 - Col. 2, l 1); "apparatus for affixing an endoluminal medical device within the tubular structures of the body" (Col. 2, ll 10-11, 36-37); "delivered to the appropriate location in the tubular structure" (Col. 3, ll 47-48) **Rogers '024:** "An intraluminal stenting graft for

	implantation in a blood vessel" (Abstract; *see also* Col. 2, ll 47, 51, 56, and 63; etc.)
[14a-1] a) a cuff having a collapsible lumen, an inner surface	**Samuels '851:** "inner surface of an inflatable balloon cuff **10**…" (Col. 2, ll 40-42); **Rogers '024:** "intraluminal stenting graft includes a collapsible tube member having a first end and a second end. An outer layer and an inner layer extend between the ends." (Abstract); *see also* Col. 1, ll 8, 23, and 66-67; Col. 3, l 20; "As shown in FIGS. **1**, **2**, and **4**, the outer layer **18** is joined to the inner layer **20** to form a plurality of cylinders **30**…the tube member **12** can include a radially extending chamber **32** that is in communication with the plurality of cylinders **30**." (Col. 2, ll 33-39); "….fluid causes the collapsed tube member **12** to expand" (Col. 2, ll 46-47)
[14a-2] and a friction-enhancing outer surface	**Samuels '851:** " inflatable balloon cuff **10** which includes a plurality of reinforced recesses **12** radially arrayed around its outer surface **14**." (Col. 2, ll 40-42); "As more precisely shown in FIGS. **3** … the recesses **12** are dome-shaped when the cuff is fully inflated." (Col. 2, ll 57-59; FIG. 3) **Rogers '024:** "….plurality of cylinders **30**…maintain the tube member **12** in a stable, expanded condition for implantation in a blood vessel" (Col. 3, ll 7-10)
[14a-3] with an inflatable and deflatable chamber disposed therebetween,	**Samuels '851:** "Inflatable balloon cuff **10** which includes a plurality of reinforced recesses **12** radially arrayed around its outer surface **14**" (Col. 2, ll 39-42); "The cuff **10** is inflated and deflated" (Col. 2, ll 65-66; *See* also Col. 4, ll 6-9). **Rogers '024:** "intraluminal stenting graft includes a collapsible tube member having a first end and a second end. An outer layer and an inner layer extend between the ends." (Abstract); *see also* Col. 1, ll 8, 23, and 66-67; Col. 3, l 20; "….the tube member **12** can include a radially extending chamber **32** that is in communication with the plurality of cylinders **30**" (Col. 2, ll 37-39; *see also* Col. 2, l 41); "….fluid causes the collapsed tube member **12** to expand" (Col. 2, ll 46-47)
[14a-4] the cuff also having an inflation port in	**Samuels '851:** "The cuff **10** is inflated and deflated by means of valve **20** (FIGS. **5** and **6**) which is integral with a side of cuff **10**" (Col. 2, ll 65-67); *Compare* Samuels '851, Fig. 1, element 20 with Samuels '575, element 39

fluid communication with the inflatable chamber,	**Rogers '024:** "Referring to FIG. **1**, the tube member **12** can include an opening **40** in the first end wall **22**. The opening **40** can receive a fluid, such as air." (Col. 2, ll 43-46); FIG. 1; "Fluid from the conduit **44** is introduced through the opening **40** and into the chamber **32**" (Col. 3, ll 25-26)
[14b-1] b) said friction-enhancing outer surface featuring inflatable protrusion(s) including at least one circumferential ridge disposed about the inflatable cuff and	**Samuels '851:** "cuff **10** which includes a plurality of reinforced recesses **12** radially arrayed around its outer surface **14**" (Col. 2, ll 40-42); "When the cuff **10** is fully inflated, the recesses **12** pop out …." (Col. 2, ll 62-63) **Rogers '024:** Cylinder(s) 30 (*See* Col. 2, ll 33-36; FIG. 1)
[14b-2] affixing the cuff with the lumen of the tubular structure without penetration of the tubular structure when the cuff is fully inflated so that movement of the cuff in a longitudinal direction with respect to the tubular structure is prevented;	**Samuels '851:** "it is an object of the present invention to provide a method in which medical devices can be affixed to tubular structure's walls without causing damage thereto and to prevent migration of the device after it has been affixed" (Col. 2, ll 2-6); "When the cuff **10** is fully inflated, the recesses **12** pop out to allow the barbs **18** to engage. . ." (Col. 2, ll 62-64) **Rogers '024:** "plurality of cylinders **30**…cooperate to maintain the tube member **12** in a stable, expanded condition for implantation in a blood vessel" (Col. 3, ll 7-10); "…the fluid causes the collapsed tube member **12** to expand for implantation in a blood vessel" (Col. 2, ll 45-48); "The stenting graft **10** allows blood flow… **at the site of implantation**…." (Col. 3, ll 32-33) (emphasis supplied); "…intraluminal stenting graft for implantation…" (Col. 4, l 23, Claim 1)
[14c] c) means for inflating the cuff with inflation material in fluid communication with said inflation port; and	**Samuels '851:** "Referring back to FIG. **1**, the cuff **10** is inflated by means of an inflation syringe **32** with an inflation material **34**…. Typically, the inflation syringe **32** is mounted in a screw-feed pressure generating device provided with a manometer…" (Col. 4, ll 10-19); "….inflation tubuing **22**. Tubing **22** … Inflation material **34** is used to inflate the cuff **10**…" (Col. 3, ll 2-8) **Rogers '024:** "The opening **40** can receive a fluid, such as

	air….The fluid can be introduced into the tube member **12** … by a fluid conduit **44**." (Col. 2, ll 44-54); FIGS. 1 and 3
[14d] d) a valve integral with said inflation port for permitting entry of the inflation material from the means for inflating and thereafter sealing said cuff to prevent deflation.	**Samuels '851:** "The cuff **10** is inflated and deflated by means of a valve **20** (Figs. 5 & 6)" (Col. 2, ll 65-66; *see also* Col. 4, ll 6-9); "The cuff **10** is inflated and deflated by means of valve **20** (FIGS. **5** and **6**) which is integral with a side of cuff **10**. Preferably, valve **20** is a duck bill valve. Duck bill valve **20** is comprised of opposing leaflets **21**…and is used in conjunction with inflation tubing **22**. Tubing **22** is inserted into the valve **20** to separate the opposing leaflets **21** of the valve **20** when the cuff is to be inflated or deflated. After the cuff **10** has been fully inflated, the tubing **22** is removed and the opposing leaflets **21** close to seal the inflated cuff **10**. Inflation material **34** is used to inflate the cuff **10**…." (Col. 2, l 65 to Col. 3, l 8) **Rogers '024:** "The opening **40** can receive a fluid, such as air.... As shown in FIG. **3**, a one-way valve **42**, such as a check valve, can be positioned in the opening **40**. The valve **42** allows for the introduction of the fluid into the tube member **12**. The valve prevents the escape of the fluid from the tube member **12** after introduction into the tube member." (Col. 2, ll 44-53); FIG. 3; "a valve positioned in said opening to allow for introduction of said fluid into said tube member and to prevent escape of said fluid from said tube member" (Col. 4, ll 41-43)
[15] 15. The apparatus of claim 14 wherein the friction-enhancing outer surface is a coarse surface.	**Samuels '851**: "inner surface of an inflatable balloon cuff **10** which includes a plurality of reinforced recesses **12** radially arrayed around its outer surface **14**." (Col. 2, ll 40-42); "As shown more precisely in FIGS. **3** … the recesses **12** are dome-shaped when the cuff is fully inflated." (Col. 2, ll 57-59; FIG. 3) **Rogers '024**: "plurality of cylinders **30**" (Col. 2, l 34); *see also*, e.g., FIG. 1 (showing indentations)
[16] 16. The inflatable intraluminal stent of claim 14 wherein the friction-enhancing outer surface is	**Rogers '024:** "outer layer 18…polytetrafluoroethylene" (Col. 2, ll 55-58)

constructed of a material that promotes tissue ingrowth.	
[17] 17. The inflatable intraluminal stent of claim 10 wherein the material that promotes tissue ingrowth is TEFLON.	**Rogers '024:** "Referring to FIG. **2**, the outer layer **18** and the inner layer **20** are composed of a polymer material that is biocompatible. An example of such a material is polytetrafluoroethylene." (Col. 2, ll 55-58) [Teflon® is a trademark for polytetrafluoroethylene.]
[18] 18. The apparatus of claim 14 wherein the valve is a mitre valve.	**Samuels '851:** "duck bill valve" (Col. 2, ll 25-28); "Preferably, valve **20** is a duck bill valve." (Col. 2, l 67) ["a 'duck bill' or 'mitre' [*sic* - mitral] valve" (**Samuels '575**, col. 4, ll 11-12.)]
[19] 19. The apparatus of claim 14 wherein the valve is of a breakaway design to permit separation from the means for inflating.	**Samuels '851:** "pullaway detachable valve….When a pullaway valve is used, the cuff **10** is inflated and deflated at low pressure to confirm its position and then is fully inflated at a higher pressure. After the inflation material **34** inside the cuff is slightly hardened, the operator of the device pulls on the inflation tubing to break connection with the cuff where the lumen is thinnest." (Col. 3, ll 15-23)
[20] 20. The apparatus of claim 14 further comprising means for securing an intraluminal medical device to the inner surface of the cuff.	**Samuels '851:** "The first step in using the present invention is to secure the medical device to the inflatable cuff **10** by means of biologically inert adhesives…." (Col. 3, ll 43-46)
[21] 21. The inflatable intraluminal stent of claim 20 wherein the intraluminal medical	**Samuels '851:** "The present invention relates generally to the field of surgical and interventional radiological techniques and more particularly to a method and apparatus for affixing an endoluminal device to the walls of tubular structures within the body. Examples of such structures are . . . blood vessels ….aneurysms…." (Col. 1, ll 8-17)

device is a graft for repairing aneurysms.	**Rogers '024:** "The present invention is directed to an intraluminal stenting graft… Intraluminal stenting grafts are implanted in a blood vessel to repair, for example, aortic aneurysms." (Col. 1, ll 5-15)
[22] 22. The inflatable intraluminal stent of claim 20 wherein the intraluminal medical device is a vena cava filter.	**Samuels '851:** "A non-exhaustive list of examples of applications of the present invention include: placing filters in the inferior vena cava . . . . A single cuff is used to secure a vena cava filter to a vessel wall." (Col. 3, ll 26-33)
[23] 23. An apparatus for disposition within the lumen of a tubular structure within the lumen body comprising:	**Samuels '851:** "apparatus for affixing an endoluminal device to the walls of tubular structures within the body" (Abstract; Col. 1, ll 10-13; Col. 1, l 67 to Col. 2, l 1); "apparatus for affixing an endoluminal medical device within the tubular structures of the body" (Col. 2, ll 10-11, 36-37); "delivered to the appropriate location in the tubular structure" (Col. 3, ll 47-48)
[23a-1] a) a plurality of cuffs,	**Samuels '851:** "Referring to FIG.**7**, a side view of a ganged arrangement of three inflatable cuffs is shown. A gang of inflatable cuffs preferably is used..." (Col. 3, ll. 33-36)
[23a-2] each of said plurality of cuffs having an inner surface and a friction enhancing outer surface with an inflatable chamber disposed therebetween,	**Samuels '851:** "the cuffs **10A-10C** … all three can be simultaneously inflated and deflated with inflation material **34**." (Col. 3, ll 38-43); "…inner surface of an inflatable balloon cuff **10** which includes a plurality of reinforced recesses **12** radially arrayed around its outer surface **14**" (Col. 2, ll 39-42);
[23a-3] the inflatable chambers of said plurality of cuffs being in fluid communication with one another;	**Samuels '851:** "Cuff **10A** …is connected to cuff **10B** via spine **50**, cuff **10B** being connected to cuff **10C** via spine **52**. The spines **50** and **52** interconnect the cuffs **10A-10C** such that all three can be simultaneously inflated and deflated with inflation material **34**." (Col. 3, ll. 37-43)

[23b-1] said friction-enhancing outer surfaces featuring inflatable protrusion(s including at least one circumferential ridge disposed about the inflatable cuff	**Samuels '851:** "cuff **10** which includes a plurality of reinforced recesses **12** radially arrayed around its outer surface **14**" (Col. 2, ll 40-42); "When the cuff **10** is fully inflated, the recesses **12** pop out to allow the barbs **18** to engage..." (Col. 2, ll 63-64)
[23b-2] and affixing the plurality of cuffs within the lumen of the tubular structure without penetration of the tubular structure when the plurality of cuffs are inflated;	**Samuels '851:** "Referring to FIG. **3**, a sectional view of a partially inflated inflatable cuff **10** is illustrated showing the engagement of its outer surface **14** with the structure's wall when the barbs **18** are inside the recesses. FIG. **3** highlights a unique feature of the present invention which is its capability of being optimally positioned within the tubular structure in the body without causing damage to the surrounding tissue. Specifically, when the balloon cuff **10** is at lower levels of inflation and after it has been inserted into the body by catheterization, the outer surface **14** holds the cuff **10** in place against the wall **30** …." (Col. 3, l 57 - Col. 4, l 2).
[23c] c) means for inflating the plurality of cuffs with inflation material; and	**Samuels '851:** "Referring back to Fig. 2, the cuff **10** is inflated by means of an inflation syringe **32** with an inflation material **34**…." (Col. 4, ll 10-12); "inflation tubing" (Col. 3, l 2)
[23d] d) a valve integral with one of the plurality of cuffs for permitting entry of the inflation material from the means for inflating and thereafter sealing said cuff to prevent deflation.	**Samuels '851:** "The cuff **10** is inflated and deflated by means of valve **20** (FIGS. **5** and **6**) which is integral with a side of cuff **10**. … inflation tubing **22**….After the cuff **10** has been fully inflated, the tubing **22** is removed and the opposing leaflets **21** close to seal the inflated cuff **10**. Inflation material **34** is used to inflate the cuff **10**…." (Col. 2, l 65 – Col. 3, l 8)

[24] 24. The apparatus of claim 22 further comprising means for securing an intraluminal medical device to the inner surfaces of the cuffs.	**Samuels '851:** "The medical device…is secured to the inner surface of an inflatable balloon cuff **10**…" (Col. 2, ll 39-41); "The first step in using the present invention is to secure the medical device to the inflatable cuff **10** by means of biologically inert adhesives…." (Col. 3, ll 43-46)

2. Claims Chart II for Grounds 4 - 8.

Samuels '575 Has Claims 1-24	**Ground 4: §103(a) Samuels '851 and Lazarus '088** [Claims 1-2 and 4-22] **Ground 5: §103(a) Samuels '851 and Rhodes '117** [Claims 1-2, 4-16, and 18- 24] **Ground 6: §103(a) Samuels '851 and Lane '029 or Miller '767 or Todd '745 or Sisson '505** [Claims 1-2, 6-15, and 18-24] **Ground 7: §103(a) Lazarus and Miller '767 or Todd '745 or Sisson '505** [Claims 1, 4-6, 9-11, 13-14, 16-17, and 19-21] **Ground 8: §103(a) Holman '537 and Pigott '620 and Lane '029** [Claims 1-2, 4-8, 11, 13-18, 21]
[1] 1. An inflatable intraluminal stent adapted to be secured to the interior of a tubular structure within the human body comprising:	**Samuels '851:** See disclosure in Claims Chart I above. **Lazarus '088:** Intraluminal vascular graft "deployable within a vessel" (Abstract); "…. toroidal collar having an internal inflatable space" (Col. 6, ll 39-40) **Pigott '620: "**intraluminal graft/stent … for … treatment of aortic aneurysms and diseased blood vessels" (Col. 1, ll-12); "intraluminal graft/stent…for implantation in a blood vessel" (Col. 2, ll 31-33); "intraluminal graft **10** is firmly engaged in blood vessel A…" (Col. 7, l 52); FIGS. 1 and 2 **Holman '537:** "surgical graft that can be fixated in a vessel such as the aorta." (Col. 2, ll 30-31); "intraluminal graft of the present invention" (Col. 1, ll 36-37); *see also* (Col. 2, ll 55-57*),* (Col. 3, l 31), (Col. 6, ll 9-11); "vascular graft apparatus" (Col. 6, l 48; Col. 7, l 15; Col. 8, l 9); *see also* FIGS. 1-5

	Rhodes '117: "An intraluminal prosthesis for introduction within a portion of a blood vessel, duct or lumen of a living being...." (Col. 11, lines 58-59); *see also*, Abstract; Col. 3, ll 18-21; Col. 4, ll 48-51); "outer balloon 24 is then inflated …." (Col. 9, ll 60-61) **Lane '029:** Laryngeal stent (Abstract); "The chamber **22** of stent **10** … is air-filled to inflate the envelope **12**…." (Col. 2, ll 61-62)
[1a-1] a) an inflatable and deflatable cuff of generally hollow cylindrical continuation having a collapsible lumen, an inner surface, an inlet, an outlet and	**Samuels '851:** See disclosure in Claims Chart I above. **Lazarus '088:** Intraluminal vascular graft "deployable within a vessel." (Abstract; etc.); "…. toroidal collar having an internal inflatable space" (Col. 6, ll 39-40); FIG. 3; "[t]he attachment means is made of a flexible material which renders it suitable for compression prior to deployment and expandable again upon deployment to extend to the full circumferential dimension of the inner surface of the vessel." (Col. 5, ll 31-35) **Pigott '620:** "spaced apart inner and outer tubes **12** and **14** …." (Col. 4, ll 5-7); "inflow aperture **22**, to which is attached an inflow valve **23**, and an outflow aperture (not shown) to which is attached an outflow valve **24**." (Col. 4, ll 48-51); "space between the inner tube **12** and outer tube **14**" (Col. 4, ll 23-25); "chamber **16** between the inner tube **12** and outer tube **14** has been filled with plastic material such as an acrylic to form an interior reinforcing layer **25**…." (Col. 5, ll 2-7); "the graft **10** in collapsed and unfilled condition to the site of implantation and for introducing air and thereafter plastic into the chamber **16**" (Col. 5, ll 52-54); *see also* (Col. 5, ll 59-60), (Col. 6, ll 33-35), (Col. 7, l 5) **Holman '537**: "graft may be expanded" (Col. 3, l 31); "hardening means causes the at least one exterior conduit to assume an expanded, rigid configuration…." (Col. 6, ll 9-11); "circular conduits or tubes **22**, **24**" (Col. 3, l 11); "end tubes **22**, **24**" (Col. 3, l 24); "FIG. 1 shows … vascular graft … in a folded state..." (Col. 2, ll 19-20); "Each conduit **22**, **24** has at least one inlet port **26** and at least one outlet or exhaust port **28**…" (Col. 3, ll 12-13); *see also* FIGS. 1-5 **Rhodes '117:** "Outer balloon means basically comprises an annular member having a cylindrical inner wall **70**, a

	generally cylindrical outer wall **72**, and interconnecting end wall portions **74** and **76** (FIG. **9**) defining a hollow space **78** (FIGS. **5** and **9**) therebetween…An self-sealing port **80** (FIG. 9) is provided in the balloon…." (Col. 8, ll 29-43; FIGS. 1, 2, 5, 6, and 9); "The outer balloon **24** is then inflated…." (Col. 9, ll 61-63); **Lane '029**: The chamber **22**…is air filled to inflate the envelope **12**…volume of air within chamber **22** is reduced during insertion and removal of the stent… " (Col. 2, ll 61 – Col. 3, ll 5-7); the volume of the chamber **22** in the stent may be decreased during insertion by squeezing the stent to express air …." (col. 4, ll 35-38)
[1a-2] a friction enhancing outer surface, said friction-enhancing outer surface	**Samuels '851:** See disclosure in Claims Chart I above. **Lazarus '088:** Collar may be "treated or fabricated with substances or materials which promote healing…to promote the attachment and incorporation of tissue and other materials into the attachment means … Fibrinogen …triggers thrombosis, and an acute or chronic healing response results in the sealing of the graft **10** to the vessel wall." (Col. 13, ll 26-39, 34, 37-39) **Lane '029:** "the surface of the envelope is coarse" (Abstract); "As shown in FIGS. **4-6**, the outer surface textures of the envelopes **12, 42, 44**, are advantageously provided with a plurality of raised points or bumps **68** (FIG. 4), ridges **70** (FIG. 5) or an otherwise coarse texture **72** (as shown in FIG. 6)" (Col. 5, ll 19-23; FIGS. 4-6); "outer surface of the first envelope is frictional" (Col. 6, ll 51-54, Claim 5)
[1a-3] featuring inflatable protrusion(s) including at least one circumferential ridge disposed about the inflatable cuff,	**Samuels '851:** See disclosure in Claims Chart I above. **Rhodes '117:** "projections need not include sharp edges and/or planar surfaces or points … they can be rounded, domed, or any other suitable shape…." (Col. 8, ll 15-22) **Lane '029:** "As shown in FIGS. 4-6, the outer surface textures of the envelopes **12**, **42**, **44**, are advantageously provided with a plurality of raised points or bumps **68** (FIG. 4), ridges **70** (FIG. 5) or an otherwise coarse texture **72** (as shown in FIG. 6)." (See Col. 5, ll 19-23; FIGS. 4-6) **Miller '767:** "Mounted upon the tube **16** are spaced cuffs **18** which …. [E]ach has a generally cylindrical shape, although

	other vessel wall engaging shapes may also be achieved with the cuff structure of the present invention. Each cuff includes an outer surface layer **20** which is impervious to gases or liquids and a resilient sponge-like, reticulated filler material **22** which fills the space between the tube **16** and the surface layer **20**." (Col. 3, ll 18-31; FIG. 1) **Todd '745:** "FIG. **7** illustrates protuberances in the form of an outwardly projecting spiral ridge **48** wound about the exterior surface of balloon **26**. When inflated, the spiral ridge **48** contacts and tightly grips the walls of a body passageway in which it is inserted." (Col. 7, ll 35-39; FIG. 7) **Sisson '505: "**retention cuffs **12** and **13**" (Col. 3, l 18); "inflatable retention cuffs" (Col. 4, l 36)
[1a-4] said friction-enhancing outer surface engaging the interior of the tubular structure without penetration to prevent the cuff from moving in a longitudinal direction with respect to the tubular structure when said cuff is in a fully inflated condition;	**Samuels '851:** See disclosure in Claims Chart I above. **Lazarus '088**: "hooks or barbs may damage the vessel, particularly where the vessel is weakened already by an aneurysm or other disease condition" (Col. 1, ll 57-60); "….it would be advantageous to provide an intraluminal graft which is adapted for use in vascular repair under any conditions, but particularly under conditions which limit or prevent the use of intraluminal grafts having hook, pin, barb or staple attachment means" (Col. 2, ll 14-18); "Fixed attachment of the graft tube to the interior of the vessel, or the intima is provided by non-puncturing attachment means secured to the outer surface of the biocompatible tube." (Col. 5, ll 17-20) **Rhodes '117**: "penetration may not be necessary for good resistance to migration of the prosthesis" (Col. 7, ll 61-62); "projections need not include sharp edges and/or planar surfaces or points … they can be rounded, domed or any other suitable shape…." (Col. 8, ll 15-22); "this action causes the projections to tightly engage (and not necessarily penetrate) the interior of the wall of the vessel, duct, or lumen to fixedly secure the prosthesis in place against migration" (Col. 8, ll 23-27); "height of the projections is selected so that their penetrating points do not penetrate too deeply into the medial or adventitial layers of the artery wall" (Col. 7, ll 65-67); "as a general proposition, the more projections utilized the less 'penetration' or 'burrowing' will necessary [sic] for

	good securement against migration." (Col. 8, ll 8-10) **Lane:** "the stent conforms so closely to the anatomical features of the larynx that sutures are not required to anchor the stent in place" (Abstract); "As shown in FIGS. **4-6**, the outer surface textures of the envelopes **12**, **42**, **44**, are advantageously provided with a plurality of raised points or bumps **68** (FIG. 4), ridges **70** (FIG. 5) or an otherwise coarse texture **72** (as shown in FIG. 6). Surface characteristics … allow for a more positive anchoring of the stent within the zones of the larynx by providing frictional engagement therewith." (Col. 5, ll 19-26) **Miller '767:** "spaced cuffs **18** which are positioned to engage the walls of the blood vessel **12** on either side of the aneurism **14**" (Col. 3, ll 18-20; *see also* FIGS. 1, 3) **Todd '745: "**When inflated, the spiral ridge **48** contacts and tightly grips the walls of a body passageway in which it is inserted." (Col. 7, ll 37-40; FIG. 7); **Sisson '505:** "inflating at least one of the inflatable retention cuffs to secure the stent in position…" (Col. 4, ll 36-37)
[1b] b) means for injecting an inflation material into said cuff to inflate it; and	**Samuels '851:** See disclosure in Claims Chart I above. **Lazarus '088:** "…means for inflating the toroidal collars **50** with a fluid from external the patient's body, is illustrated in FIGS. **3** and **4** where an inflation conduit **56** is attached…" (Col. 15, ll 15-18; Col. 15, ll 24-28); "Any suitable fluid may be introduced into the internal space of the attachment means, be it liquid or gas…." (Col. 7, ll 27-28) **Piggott '620:** "syringe **60**" (Col. 6, l 23); "…the flexible tube **54** is ready to introduce fluid into the chamber **16** between the inner tube **12** and outer tube **14**….air is injected into the passageway **53** by depressing the plunger **63** …." (Col. 6, ll 41-43, 50-51); FIG. 3 **Holman '537:** "The chemical hardening means may be a polymeric material introduced through the introduction means through an external source, such as a … syringe.' (Col. 1, ll 48-50); "Each conduit **22, 24** has at last one inlet port **26** and at least one outlet or exhaust port **28**, inlet(s) **26** being connected to elongated introduction means **30**,**32** respectively." (Col. 3, ll 12-15); "introduction of chemical hardening via syringe" (Col. 2, ll 26-27); *see also* FIG. 3.

	Rhodes '117: "tube or conduit **82** extending from outside the body of the patient. The conduit **82** is arranged to carry a fluid, e.g., a gel or saline solution **84** (FIG. 5), therethrough for introduction through the port **80** into the interior **78** of the balloon to inflate the balloon." (Col. 8, ll 44-48); FIG. 5 **Lane '029:** "Inflation may be carried out by inserting a cannula...through a self-sealing…portal **26** in the end **20** of the envelope, connected with a pump (syringe) suitable for moving air under pressure into the chamber **22**." (Col., 2, ll 63-67); FIG. 1
[1c] c) a valve integral with the inflatable cuff for permitting entry of the inflation material from the means for injecting and thereafter sealing said cuff to prevent deflation.	**Samuels '851:** See disclosure in Claims Chart I above. **Lazarus '088:** "The valve **58** includes as opening **62** therethrough, as best seen in FIG. **4**, which provides passage of a fluid from the inflation conduit **56** into the internal space **52** of the toroidal collar **50**." (Col. 15, ll 21-24; see also FIG. 4); "Upon removal of the inflation conduit, the valve automatically closes sealing the fluid within the internal space **52** of the toroidal collar **50**." (Col. 15, ll 31-33) **Piggott '620:** "The outer tube **14** is provided with an inflow aperture **22**, to which is attached an inflow valve **23**…The inflow valve **23** provides means for introducing both pressurized air and subsequently plastic material into the chamber **16** between the inner tube **12** and outer tube **14**." (Col. 4, ll 48-54); "the valve **32** functions effectively as a one-way valve permitting the flow of fluid there through and into the chamber **16** but preventing the outflow from such chamber …." (Col. 5, ll 36-41) **Rhodes '117:** "An self-sealing port **80**[*sic*] (FIG. 9) is provided in the balloon ….." (Col. 8, ll 42-43); "self-sealing port **80** closes to trap the fluid **84** within the balloon, thereby keeping the balloon inflated." (Col. 8, ll 62-63).
[2] 2. The inflatable intraluminal stent of claim 1 wherein the friction-enhancing outer surface is a coarse surface.	**Samuels '851:** See disclosure in Claims Chart I above. **Rhodes '117:** "a sealing mesh covering…, extending over substantially the entire exterior surface of the outer balloon …." (Col. 10, ll 51-54) **Lane '029:** "the surface of the envelope is coarse" (Abstract)

[3] 3. The . . . stent of claim 1 . . . a plurality of spot welds. . . . [For complete text see Claims Chart 1]	
[4] 4. The inflatable intraluminal stent of claim 1 wherein the friction-enhancing outer surface is constructed of a material that promotes tissue ingrowth.	**Lazarus '088:** "The material of the attachment means is formed from material which is, or is otherwise treated to be, porous and/or textured to promote the attachment or ingrowth of tissue into the attachment means thereby incorporating at least a portion of the intraluminal vascular graft into the vessel." (Col. 5, ll 35-40); "The attachment means may also be treated, such as by coating or infusion, with a substance or material which promotes attachment of the vessel to the graft. Such substances may promote healing or ingrowth of tissue into the attachment means…." (Col. 6, ll 6-10) **Piggott '620:** "spaced apart inner and outer tubes **12** and **14** respectively formed of …. Gore-Tex® (polytetrafluoroethylene) …." (Col. 4, ll 5-11) **Holman '537:** "Fabrics from which sleeve **10** may be made are … polytetrafluoroethylene (PTFE)…. The most preferred materials are … PTFE" (Col. 2, ll 64-Col. 3, l 4) **Rhodes '117:** "a sealing mesh covering…extending over substantially the entire exterior surface of the outer balloon…." (Col. 10, ll 51-54); "since the mesh covering is thrombogenic and fibrogenic it stimulates the incorporation of the prosthesis **20** by fibrosis to the aortic wall, thus ensuring a complete and permanent seal" (Col. 11, ll 31-34)
[5] 5. The inflatable intraluminal stent of claim 4 wherein the material that promotes tissue ingrowth is TEFLON.	**Lazarus '088:** "The tubular body **12** may be formed from any suitable biocompatible material, including . . . polytetrafluoroethylene [*sic*]." (Col. 11, ll 4-6) **Pigott '620:** "spaced apart inner and outer tubes **12** and **14** respectively formed of …. Gore-Tex® (polytetrafluoroethylene) …." (Col. 4, ll 5-11) **Holman '537:** "Fabrics from which sleeve **10** may be made are … polytetrafluoroethylene (PTFE) …. The most preferred materials are … PTFE" (Col. 2, l 64-Col. 3, l 4) **Rhodes '117:** "The prosthesis 20 basically comprises sleeve means **22** . . . . The tubular sleeve member **32** is formed of a

	thin and highly flexible material, such as expanded polytetrafluoroethylene, used for conventional vascular grafts." (Col. 5, ll. 23-32) [Teflon® and Gore-Tex® are trademarks for polytetrafluoroethylene.]
[6] 6. The inflatable intraluminal stent of claim 1 wherein the inflatable cuff is composed of a polymeric plastic which is biologically inert.	**Samuels '851:** See disclosure in Claims Chart I above. **Lazarus '088:** "The tubular body **12** may be formed from any suitable biocompatible material including . . . polytetrafluoroethylene [*sic*]" (Col. 11, ll 4-6); *see also*, Col. 3, ll. 5-7 **Holman '537:** "Sleeve **10** is made of a biocompatible polymeric material." (Col. 2, ll 63-64); "The device is made of polymeric material…." (Col. 5, ll 19-20) **Rhodes '117:** "The balloon is an integral unit, preferably formed of a very flexible material, such as that typically used in conventional balloon catheters." (Col. 8, ll 34-36) **Lane '029**: "a film of a medical grade [Food and Drug Administration (FDA) approved] synthetic polymer resin." (Col. 2, ll 45-47); "block copolymers" (Col. 3, l 20-Col.4, l 12)
[7] 7. The inflatable intraluminal stent of claim 1 wherein the inflation material includes a hardening agent.	**Samuels '851:** See disclosure in Claims Chart I above. **Pigott '620:** "chamber **16** between the inner tube **12** and outer tube **14** has been filled with plastic material such as an acrylic to form an interior reinforcing layer **25**". (Col.5,ll3-5) **Holman '537: "**The collapsed sleeve may be made rigid and circular by the introduction through the introduction means of a chemical or mechanical hardening means. The chemical hardening means… may be a polymeric material." (Col. 1, ll 44-49); "The chemical hardening means may be introduced in the form of an injectable polymeric material…" (Col. 3, ll 37-38); "activatable hardening material" (*See, e.g.*, Col. 4, l 19); "hardening means" (*See, e.g.*, Col. 6, ll 9-10) **Rhodes '117:** "The conduit **82** is arranged to carry a fluid, e.g., a gel or saline solution **84** (FIG. 5)" (Col. 8, ll 45-48; FIG. 5); "If desired the fluid may be a 'settable' fluid or gel to further stiffen the prosthesis" (Col. 8, ll 66-67); "outer balloon **24** is filled sufficiently to create the desired rigidity" (Col. 9, ll 66-67)
[8] 8. The inflatable	**Samuels '851:** See disclosure in Claims Chart I above. **Pigott '620:** " one-way valve **32** … terminating in a pair of

intraluminal stent of claim 1 wherein the valve is a mitre valve.	lips **35**. The lips **35** are normally in sealing engagement with one another but may readily be opened…. (Col. 5, ll 23-27) ["a 'duck bill' or 'mitre' [*sic* - mitral] valve" (**Samuels '575**, col. 4, ll 11-12.)]
[9] 9. The inflatable intraluminal stent of claim 1 wherein the valve is of a breakaway design to permit separation from the means for injecting.	**Samuels '851:** See disclosure in Claims Chart I above. **Lazarus '088:** "the conduit is detached from the attachment means, whereupon a valve means is caused to close and seal off the internal space of the attachment means" (Col. 7, ll 30-33); "The inflation conduit **56** may then be removed from the valve **58**, such as by pulling or gently turning the inflation conduit **56** to dislodge it from the valve **58**. Upon removal of the inflation conduit **56**…." (Col. 15, ll 28-32)
[10] 10. The inflatable intraluminal stent of claim 1 further comprising means for securing an intraluminal medical device to the inner surface of the inflatable cuff.	**Samuels '851:** See disclosure in Claims Chart I above. **Lazarus '088:** "The expandable circumferential support structures and the adjustable longitudinal structures generally comprise what may be called the frame of the graft structure. The frame is secured to the biocompatible graft tube by any suitable means, such as tacking or sewing the frame to the tube, or by weaving the frame into the tube." (Col. 4, l 64 to Col. 5, l 18) **Rhodes '117:** "The inner surface of the inner wall **70** of the balloon is fixedly secured by any suitable means, e.g., an adhesive…to the outer surface of the sleeve member" (Col. 8, ll 38-40)
[11] 11. The inflatable intraluminal stent of claim 10 wherein the intraluminal medical device is a graft for repairing aneurysms.	**Samuels '851:** See disclosure in Claims Chart I above. **Lazarus '088:** "This invention relates to medical devices in general, and specifically to grafts positionable intraluminally for repairing aneurysms or other vascular defects in humans and animals." (Col. 1, ll. 11-14) **Pigott '620:** "intraluminal graft/stent…for non-invasive treatment of aortic aneurysms…." (Col. 1, ll 9-11) **Holman '537:** "The present invention provides devices for repairing aortic aneurysms…." (Col. 1, ll 34-36) **Rhodes '117:** "The prosthesis is arranged for introduction within a portion of a blood vessel, duct or lumen, e.g., the abdominal aorta, of a living being having an aneurysm in the wall. The prosthesis basically comprises sleeve means…." (Col. 3, ll 18-23)

[12] 12. The inflatable intraluminal stent of claim 10 wherein the intraluminal medical device is a vena cava filter.	**Samuels '851:** See disclosure in Claims Chart I above.
[13] 13. The inflatable intraluminal stent of claim 1 wherein the means for injecting an inflation material into said inflatable cuff to inflate it includes an inflation syringe and inflation tubing.	**Samuels '851:** See disclosure in Claims Chart I above. **Lazarus '088:** "Another example of a means for inflating the toroidal collars **50** with a fluid, from external the patient's body, is illustrated in FIGS. 3 and 4 where an inflation conduit **56** is attached …." (Col. 15, ll 15-18; FIGS. 3 and 4) **Holman '537:** "The chemical hardening means may be a polymeric material introduced through the introduction means through an external source, such as a … syringe.' (Col. 1, ll 48-50); "Each conduit **22, 24** has at least one inlet port **26** and at least one outlet or exhaust port **28**, inlet(s) **26** being connected to elongated introduction means **30**, **32** respectively." (Col. 3, ll 12-15); "introduction of chemical hardening material via syringe" (Col. 2, ll 26-27); FIG. 3. **Rhodes '117:** "The conduit **82** is arranged to carry a fluid, e.g., a gel or saline solution **84** (FIG. 5), therethrough for introduction through the port **80** into the interior **78** of the balloon to inflate the balloon." (Col. 8, ll 45-48; FIG. 5) **Lane '029:** "Inflation may be carried out by inserting a cannula (not shown in FIG. 1) through a self-sealing … portal **26** in the end **20** of the envelope, connected with a pump (syringe) suitable for moving air under pressure into the chamber **22**." (Col. 2, ll 63-67; FIG. 1)
[14] 14. An apparatus for disposition within the lumen of a tubular structure within the human body comprising:	**Samuels '851:** See disclosure in Claims Chart I above. **Lazarus '088:** Intraluminal vascular graft "deployable within a vessel." (Abstract, etc.); "…. toroidal collar having an internal inflatable space" (Col. 6, ll 39-40) **Pigott '620:** "intraluminal graft/stent … for treatment of aortic aneurysms and diseased blood vessels" (Col. 1, ll 8-12); "intraluminal graft/stent…for implantation in a blood vessel" (Col. 2, ll 31-33); "intraluminal graft **10** is firmly engaged in blood vessel A…" (Col. 7, l 52); FIGS. 1 and 2 **Holman '537:** "surgical graft that can be fixated in a vessel

	such as the aorta" (Col. 1, ll 30-31); "….intraluminal graft of the present invention" (Col. 1, ll 36-37); "device and method for repairing an aneurysm or the like in a vessel, such as the aorta" (Col. 2, ll 55-57); "graft may be expanded" (Col. 3, l 31); "….hardening means causes the at least one exterior conduit to assume an expanded, rigid configuration which fits securely into the vessel and is anchored thereto …." (Col. 6, ll 9-11); "vascular graft apparatus" (Col. 6, l 48, Col. 7, l 15; Col. 8, l 9); *see also* FIGS. 1-5 **Rhodes '117:** "An intraluminal prosthesis for introduction within a portion of a blood vessel, duct or lumen of a living being...." (Col. 11, ll 58-59); *see also* Abstract; Col. 3, ll 18-21; Col. 4, ll 48-51) **Lane '029:** Laryngeal stent (Abstract); "The chamber **22** of stent **10** … is air-filled to inflate the envelope **12**…." (Col. 2, ll 61-62)
[14a-1] a) a cuff having a collapsible lumen, an inner surface	**Samuels '851:** See disclosure in Claims Chart I above. **Lazarus '088:** Intraluminal vascular graft "deployable within a vessel." (Abstract) **Pigott '620:** "spaced apart inner and outer tubes **12** and **14** …" (Col. 4, ll 6-7); "the graft **10** in collapsed and unfilled condition …." (Col. 5, ll 52-54); "….intraluminal graft **10** in collapsed and unfilled condition" (Col. 5, ll 59-60); "The intraluminal graft **10** is initially collapsed …." (Col. 6, ll 33-35); "intraluminal graft **10** in collapsed condition" (Col. 7, l 5) ; FIG. 2 **Holman '537**: "circular conduits or tubes **22**, **24**" (Col. 3, l 11); "end tubes **22**, **24**" (Col. 3, l 24); "FIG. **1** shows … vascular graft …in a folded state..." (Col. 2, ll 19-20); *see also* FIGS. 1-5 **Rhodes '117:** "outer balloon means basically comprises an annular member having a cylindrical inner wall **70**, a generally cylindrical outer wall **72**, and interconnecting end wall portions **74** and **76** (FIG. 9) defining a hollow space **78** (FIGS. 5 and 9) therebetween…A self-sealing port **80** (FIG. 9) is provided in the balloon…." (Col. 8, ll 29-43; FIGS. 1, 2, 5, 6, and 9); "The outer balloon **24** is then inflated…." (Col. 9, ll 61-63); The outer balloon must be collapsible (Col. 9, ll 63-66) and also must be collapsible to fit into "balloon

	catheter 8" **Lane '029**: The chamber **22**…is air filled to inflate the envelope **12**…volume of air within chamber **22** is reduced during insertion and removal of the stent…" (Col. 2, ll 61 – Col. 3, ll 5-7)
[14a-2] and a friction-enhancing outer surface	**Samuels '851:** See disclosure in Claims Chart I above. **Lazarus '088:** Collar may be "treated or fabricated with substances or materials which promote healing…to promote the attachment and incorporation of tissue and other materials into the attachment means … Fibrinogen …triggers thrombosis, and an acute or chronic healing response results in the sealing of the graft **10** to the vessel wall." (Col. 13, ll 26-30, 34, 37-39) **Lane '029:** "the surface of the envelope is coarse" (Abstract); "As shown in FIGS. **4-6**, the outer surface textures of the envelopes **12, 42, 44**, are advantageously provided with a plurality of raised points or bumps **68** (FIG. 4), ridges **70** (FIG. 5) or an otherwise coarse texture **72** (as shown in FIG. 6)." (Col. 5, ll 19-23; FIGS. 4-6); "outer surface of the first envelope is frictional" (Col. 6, ll 51-54, Claim 5)
[14a-3] with an inflatable and deflatable chamber disposed therebetween,	**Samuels '851:** See disclosure in Claims Chart I above. **Lazarus '088:** "attachment means may be a toroidal collar having an internal inflatable space…" (Col. 6, ll 39-40) **Pigott '620:** "spaced apart inner and outer tubes **12** and **14** …" (Col. 4, ll 6-7); "space between the inner tube **12** and outer tuber **14**" (Col. 4, ll 23-25); "chamber **16** between the inner tube **12** and outer tube **14** has been filled with plastic material such as an acrylic to form an interior reinforcing layer **25**…." (Col. 5, ll 2-7); "the graft **10** in collapsed and unfilled condition to the site of implantation and for introducing air and thereafter plastic into the chamber **16**" (Col. 5, ll 52-54); "intraluminal graft **10** in collapsed and unfilled condition" (Col. 5, ll 59-60); "The intraluminal graft **10** is initially collapsed …." (Col. 6, ll 33-35); "intraluminal graft **10** in collapsed condition" (Col. 7, l 5) **Holman '537**: "graft may be expanded" (Col. 3, l 31); "hardening means causes the at least one exterior conduit to assume an expanded, rigid configuration…." (Col. 6, ll 9-11);

	"circular conduits or tubes **22**, **24**" (Col. 3, l 11); "end tubes **22**, **24**" (Col. 3, l 25); "FIG. **1** shows … vascular graft … in a folded state..." (Col. 2, ll 19-20); *see also* FIGS. 1-5 **Rhodes '117:** "outer balloon means basically comprises an annular member having a cylindrical inner wall **70**, a generally cylindrical outer wall **72**, and interconnecting end wall portions **74** and **76** (FIG. 9) defining a hollow space **78** (FIGS. **5** and **9**) therebetween…." (Col. 8, ll 29-34; FIGS. 1, 2, 5, 6 , and 9); "The outer balloon 24 is then inflated…." (Col. 9, ll 60-63) **Lane '029:** The chamber **22**…is air filled to inflate the envelope **12**…volume of air within chamber **22** is reduced during insertion and removal of the stent…." (Col. 2, ll 61 – Col. 3, l 7)
[14a-4] the cuff also having an inflation port in fluid communication with the inflatable chamber,	**Samuels '851:** See disclosure in Claims Chart I above. **Lazarus '088:** "opening **62** therethrough, as best seen in FIG. **4**, which provides passage of a fluid from the inflation conduit **56** into the internal space **52** of the toroidal collar **50**." (Col. 15, ll 21-24) **Pigott '620:** "The outer tube **14** is provided with an inflow aperture **22**, to which is attached inflow valve **23** …." (Col. 4, ll 48-49) **Holman '537**: "circular conduits or tubes **22**, **24**" (Col. 3, l 11); "end tubes **22**, **24**" (Col. 3, l 25); "Each conduit **22**, **24** has at least one inlet port **26** and at least one outlet or exhaust port **28**…" (Col. 3, ll 12-13); *see also* FIGS. 1-5 **Rhodes '117:** "An self-sealing port **80** (FIG. **9**) is provided in the balloon for communication with a tube or conduit **82** extending from outside the body of the patient. The conduit **82** is arranged to carry a fluid, e.g., a gel or saline solution **84** (FIG. **5**), therethrough for introduction through the port **80** into the interior **78** of the balloon to inflate the balloon." (Col. 8, ll 42-48) **Lane '029:** "Inflation may be carried out by inserting a cannula...through a self-sealing…portal **26** in the end **20** of the envelope…." (Col. 2, ll 63-65); FIG. 1
[14b-1]	**Samuels '851:** See disclosure in Claims Chart I above. **Rhodes '117:** "projections need not include sharp edges

b) said friction-enhancing outer surface featuring inflatable protrusion(s) including at least one circumferential ridge disposed about the inflatable cuff and	and/or planar surfaces or points … they can be rounded, domed, or any other suitable shape…." (Col. 8, ll 15-22) **Lane '029:** "As shown in FIGS. 4-6, the outer surface textures of the envelopes **12, 42, 44**, are advantageously provided with a plurality of raised points or bumps **68** (FIG. **4**), ridges 70 (FIG. **5**) or an otherwise coarse texture **72** (as shown in FIG. **60**)." (*See*, Col. 5, ll 19-23; FIGS. 4-6) **Miller '767:** "Mounted upon the tube **16** are spaced cuffs **18** which …. Each has a generally cylindrical shape, although other vessel wall engaging shapes may also be achieved with the cuff structure of the present invention. Each cuff includes an outer surface layer **20** which is impervious to gases or liquids and a resilient sponge-like, reticulated filler material **22** which fills the space between the tube **16** and the surface layer **20**." (Col. 3, ll 18-31; FIG. 1) **Todd '745:** "FIG. 7 illustrates protuberances in the form of an outwardly projecting spiral ridge **48** wound about the exterior surface of balloon **26**. When inflated, the spiral ridge **48** contacts and tightly grips the walls of a body passageway in which it is inserted."(Col. 7, ll 35-39; FIG. 7). **Sisson '505: "**retention cuffs **12** and **13**" (Col. 3, l 18); "inflatable retention cuffs" (Col. 4, l 36)
[14b-2] affixing the cuff with the lumen of the tubular structure without penetration of the tubular structure when the cuff is fully inflated so that movement of the cuff in a longitudinal direction with respect to the tubular structure is prevented;	**Samuels '851:** See disclosure in Claims Chart I above. **Lazarus '088**: "hooks or barbs may damage the vessel, particularly where the vessel is weakened already by an aneurysm or other disease condition" (Col. 1, ll 57-60); "it would be advantageous to provide an intraluminal graft which is adapted for use in vascular repair under any conditions, but particularly under conditions which limit or prevent the use of intraluminal grafts having hook, pin, barb or staple attachment means" (Col. 2, ll 14-18); "Fixed attachment of the graft tube to the interior of the vessel, or the intima, is provided by non-puncturing attachment means secured to the outer surface of the biocompatible tube." (Col. 5, ll 17-20) **Holman '537:** "the hardening means causes the at least one exterior conduit to assume an expanded, rigid configuration which fits securely into the vessel and is anchored thereto by pressure, causing the sleeve to be supported in an open

	condition for fluid flow therethrough.' (Col. 6, ll 9-14) **Rhodes '117**: "penetration may not be necessary for good resistance to migration of the prosthesis" (Col. 7, ll 61-62); "projections need not include sharp edges and/or planar surfaces or points … they can be rounded, domed or any other suitable shape…." (Col. 8, ll 15-22); "this action causes the projections to tightly engage (and not necessarily penetrate) the interior of the wall of the vessel, duct, or lumen to fixedly secure the prosthesis in place against migration" (Col. 8, ll 23-27); "height of the projections is selected so that their penetrating points do not penetrate too deeply into the artery wall" (Col. 7, ll 63-67); "as a general proposition, the more projections utilized the less 'penetration' or 'burrowing' will necessary [sic] for good securement against migration" (Col. 8, ll 8-11) **Lane '029:** "the stent conforms so closely to the anatomical features of the larynx that sutures are not required to anchor the stent in place" (Abstract); "As shown in FIGS. **4-6**, the outer surface textures of the envelopes **12**, **42**, **44**, are advantageously provided with a plurality of raised points or bumps **68** (FIG. 4), ridges **70** (FIG. **5**) or an otherwise coarse texture **72** (as shown in FIG. **6**). Surface characteristics … allow for a more positive anchoring of the stent within the zones of the larynx by providing frictional engagement therewith." (Col. 5, ll 19-26) **Miller '767:** "spaced cuffs **18** which are positioned to engage the walls of the blood vessel **12** on either side of the aneurism **14**" (Col. 3, ll 18-20; *see also* FIGS. 1, 3) **Todd '745: "**When inflated, the spiral ridge **48** contacts and tightly grips the walls of a body passageway in which it is inserted." (Col. 7, ll 37-40; FIG. 7) **Sisson '505:** "inflating at least one of the inflatable retention cuffs to secure the stent in position…" (Col. 4, ll 35-37)
[14c] c) means for inflating the cuff with inflation material in fluid communication	**Samuels '851:** See disclosure in Claims Chart I above. **Lazarus '088:** "means for inflating the toroidal collars **50** with a fluid from external the patient's body, is illustrated in Figs. **3** and **4** where an inflation conduit **56** is attached…" (Col. 15, ll 14-18; Col. 15, ll 24-28); "….opening **62** therethrough, as best seen in FIG. **4**, which provides passage

with said inflation port; and	of a fluid from the inflation conduit **56** into the internal space **52** of the toroidal collar **50**." (Col. 15, ll 21-23) **Pigott '620:** "syringe **60**" (Col. 6, l 23); "…the flexible tube **54** is ready to introduce fluid into the chamber **16** between the inner tube **12** and outer tube **14**….air is injected into the passageway **53** by depressing the plunger **63** …." (Col. 6, ll 41-43); FIG. 3 **Holman '537:** "The chemical hardening means may be a polymeric material introduced through the introduction means through an external source, such as a … syringe.' (Col. 1, ll 48-50); "Each conduit **22,24** has at least one inlet port **26** and at least one outlet or exhaust port **28**, inlet(s) **26** being connected to elongated introduction means **30**, **32** respectively." (Col. 3, ll 12-15); "introduction of chemical hardening material via syringe" (Col. 2, ll 26-27); FIG. 3 **Rhodes '117:** "The conduit **82** is arranged to carry a fluid, e.g., a gel or saline solution **84** (FIG. 5) therethrough for introduction through the port **80** into the interior **78** of the balloon to inflate the balloon." (Col. 8, ll 45-48; FIG. 5) **Lane '029:** "Inflation may be carried out by inserting a cannula...through a self-sealing…portal **26** in the end **20** of the envelope, connected with a pump (syringe) suitable for moving air under pressure into the chamber **22**." (Col., 2, ll 63-67); FIG. 1
[14d] d) a valve integral with said inflation port for permitting entry of the inflation material from the means for inflating and thereafter sealing said cuff to prevent deflation.	**Samuels '851:** See disclosure in Claims Chart I above. **Lazarus '088:** "The valve **58** includes as opening **62** therethrough, as best seen in FIG. 4, which provides passage of a fluid from the inflation conduit **56** into the internal space **52** of the toroidal collar **50**." (Col. 15, ll 21-24; *see also* FIG. 4); "Upon removal of the inflation conduit, the valve automatically closes sealing the fluid within the internal space **52** of the toroidal collar **50**." (Col. 15, ll 31-36) **Pigott '620:** "The outer tube **14** is provided with an inflow aperture **22**, to which is attached an inflow valve **23**…The inflow valve **23** provides means for introducing both pressurized air and subsequently plastic material into the chamber **16** between the inner tube **12** and outer tube **14**." (Col. 4, ll 48-54); "the valve **32** functions effectively as a one-way valve permitting the flow of fluid therethrough and

	into the chamber **16** but preventing the outflow from such chamber ….” (Col. 5, ll 36-41) **Lane ’029:** “pressure relief valve **30**, which is in fluid communication with chamber **22** through flexible conduit **32** … Alternatively, valve **30** may be a pressure responsive valve permitting re-inflation of chamber **22** if there is a pressure loss and functions then to maintain inflation of the envelope **12**” (Col. 3, ll 13-20; FIGS. 1, 7)
[15] 15. The apparatus of claim 14 wherein the friction-enhancing outer surface is a coarse surface.	**Samuels ‘851:** See disclosure in Claims Chart I above. **Rhodes ‘117:** “a sealing mesh covering…, extending over substantially the entire exterior surface of the outer balloon ….” (Col. 10, ll 51-54) **Lane ‘029:** “the surface of the envelope is coarse” (Abstract)
[16] 16. The inflatable intraluminal stent of claim 14 wherein the friction-enhancing outer surface is constructed of a material that promotes tissue ingrowth.	**Lazarus ‘088:** “The material of the attachment means is formed from material which is, or is otherwise treated to be, porous and/or textured to promote the attachment or ingrowth of tissue into the attachment means thereby incorporating at least a portion of the intraluminal vascular graft into the vessel.” (Col. 5, ll 35-40); “The attachment means may also be treated, such as by coating or infusion, with a substance or material which promotes attachment of the vessel to the graft. Such substances may promote healing or ingrowth of tissue into the attachment means….” (Col. 6, ll 6-10) **Pigott ‘620:** “spaced apart inner and outer tubes **12** and **14** respectively formed of …. Gore-Tex®(polytetrafluoroethylene) ….” (Col. 4, ll 5-12) **Holman ‘537:** “Fabrics from which sleeve **10** may be made are … polytetrafluoroethylene (PTFE)…. The most preferred materials are … PTFE” (Col. 2, l 64-Col. 3, l 4) **Rhodes ‘117:** “a sealing mesh covering…extending over substantially the entire exterior surface of the outer balloon….” (Col. 10, ll 51-54); “since the mesh covering is thrombogenic and fibrogenic it stimulates the incorporation of the prosthesis **20** by fibrosis to the aortic wall, thus ensuring a complete and permanent seal” (Col. 11, ll 31-34)
[17] 17. The inflatable	**Lazarus ‘088:** “The tubular body **12** may be formed from any suitable biocompatible material, including . . . polytetrafluoroethylene.” (Col. 11, ll 4-6)

intraluminal stent of claim 10 wherein the material that promotes tissue ingrowth is TEFLON.	**Pigott '620:** "spaced apart inner and outer tubes **12** and **14** respectively formed of …. Gore-Tex®(polytetrafluoroethylene) …." (Col. 4, ll 5-12) **Holman '537:** "Fabrics from which sleeve **10** may be made are … polytetrafluoroethylene (PTFE)…. The most preferred materials are … PTFE" (Col. 2, l 64-Col. 3, l 4) [Teflon® and Gore-Tex® are trademarks for polytetrafluoroethylene.]
[18] 18. The apparatus of claim 14 wherein the valve is a mitre valve.	**Samuels '851:** See disclosure in Claims Chart I above. **Pigott '620:** " one-way valve **32** … terminating in a pair of lips **35**. The lips **35** are normally in sealing engagement with one another but may readily be opened…." (Col. 5, ll 23-27); see also FIGS. 4 and 5, and element 32. ["a 'duck bill' or 'mitre' [*sic* - mitral] valve" (**Samuels '575**, col. 4, ll 11-12.)]
[19] 19. The apparatus of claim 14 wherein the valve is of a breakaway design to permit separation from the means for inflating.	**Samuels '851:** See disclosure in Claims Chart I above. **Lazarus '088:** "the conduit is detached from the attachment means, whereupon a valve means is caused to close and seal off the internal space of the attachment means" (Col. 7, ll 30-33); "The inflation conduit **56** may then be removed from the valve **58**, such as by pulling or gently turning the inflation conduit **56** to dislodge it from the valve **58**. Upon removal of the inflation conduit **56**…." (Col. 15, ll 28-32)
[20] 20. The apparatus of claim 14 further comprising means for securing an intraluminal medical device to the inner surface of the cuff.	**Samuels '851:** See disclosure in Claims Chart I above. **Lazarus '088:** "The expandable circumferential support structures and the adjustable longitudinal structures generally comprise what may be called the frame of the graft structure. The frame is secured to the biocompatible graft tube by any suitable means, such as tacking or sewing the frame to the tube, or by weaving the frame into the tube." (Col. 4, l 64 to Col. 5, l 2) **Rhodes '117:** "The inner surface of the inner wall **70** of the balloon is fixedly secured by any suitable means, e.g., an adhesive…to the outer surface of the sleeve member **32** and the outer surface of the intermediate support stents **38** between the pair of anchoring stents **34** and **36**." (Col. 8, ll 38-42)

[21] 21. The inflatable intraluminal stent of claim 20 wherein the intraluminal medical device is a graft for repairing aneurysms.	**Samuels '851:** See disclosure in Claims Chart I above. **Lazarus '088:** "This invention relates to medical devices in general, and specifically to grafts positionable intraluminally for repairing aneurysms or other vascular defects in humans and animals." (Col. 1, ll. 11-14) **Pigott '620:** "intraluminal graft/stent … for non-invasive treatment of aortic aneurysms and diseased blood vessels" (Col. 1, ll 8-12); "intraluminal graft/stent…for implantation in a blood vessel" (Col. 2, ll 31-33); "intraluminal graft 10 is firmly engaged in blood vessel …" (Col. 7, l 52); FIGS. 1 and 2 **Holman '537:** "devices for repairing aortic aneurysms …." (Col. 1, ll 35-36) **Rhodes '117:** "The prosthesis is arranged for introduction within a portion of a blood vessel, duct or lumen, e.g., the abdominal aorta, of a living being having an aneurysm in the wall. The prosthesis basically comprises sleeve means…." (Col. 3, ll 18-23)
[22] 22. The inflatable intraluminal stent of claim 20 wherein the intraluminal medical device is a vena cava filter.	**Samuels '851:** See disclosure in Claims Chart I above.
[23] 23. An apparatus for disposition within the lumen of a tubular structure within the lumen body comprising:	**Samuels '851:** See disclosure in Claims Chart I above. **Holman '537:** "surgical graft that can be fixated in a vessel such as the aorta" (Col. 1, ll 30-31); "intraluminal graft of the present invention" (Col. 1, ll 36-37); "device and method for repairing an aneurysm or the like in a vessel, such as the aorta" (Col. 2, ll 55-57); "graft may be expanded" (Col. 3, l 31); "hardening means causes the at least one exterior conduit to assume an expanded, rigid configuration which fits securely into the vessel and is anchored thereto …. (Col. 6, ll 9-11); "vascular graft apparatus" (Col. 6, l 48; Col. 7, l 15; Col. 8, l 9); *see also* FIGS. 1-5

[23a-1] a) a plurality of cuffs,	**Samuels '851:** See disclosure in Claims Chart I above. **Holman '537:** "as shown in FIG. **4**, a series of interconnected concentric cylindrical tubules **40** attached to and encasing the sleeve **10"** (Col. 3, ll 37); FIG. 4
[23a-2] each of said plurality of cuffs having an inner surface and a friction enhancing outer surface with an inflatable chamber disposed therebetween,	**Samuels '851:** See disclosure in Claims Chart I above. **Holman '537:** "These polymers or polymeric systems would fill … tubules **40** …." (Col. 3, ll 41-42); FIG. 4
[23a-3] the inflatable chambers of said plurality of cuffs being in fluid communication with one another;	**Samuels '851:** See disclosure in Claims Chart I above. **Holman '537:** "Tubules **40** are interconnected by means of connecting tube **41** extending between the tubules." (Col. 3, ll 35-37); FIG. 4
[23b-1] b) said friction-enhancing outer surfaces featuring inflatable protrusion(s including at least one circumferential ridge disposed about the inflatable cuff	**Samuels '851:** See disclosure in Claims Chart I above. **Lane '029:** "the surface of the envelope is coarse" (Abstract); "As shown in FIGS. **4-6**, the outer surface textures of the envelopes **12, 42, 44**, are advantageously provided with a plurality of raised points or bumps **68** (FIG. **4**), ridges **70** (FIG. **5**) or an otherwise coarse texture **72** (as shown in FIG. **6**)" (Col. 5, ll 19-23; FIGS. 4-6); "outer surface of the first envelope is frictional" (Col. 6, ll 51-54, Claim 5)
[23b-2] and affixing the plurality of cuffs within the lumen of the tubular structure without penetration of the tubular structure when the plurality of cuffs are	**Samuels '851:** See disclosure in Claims Chart I above. **Holman '537:** "polymers or polymeric systems would fill … tubules 40, causing them to expand and rigidify, thereby fixing the sleeve at the site of repair." (Col. 3, 41-43)

inflated;	
[23c] c) means for inflating the plurality of cuffs with inflation material; and	**Samuels '851:** See disclosure in Claims Chart I above. **Holman '537:** "The chemical hardening means may be a polymeric material introduced through the introduction means through an external source, such as a … syringe.' (Col. 1, ll 48-50); "Each conduit **22,24** has at least one inlet port **26** and at least one outlet or exhaust port **28**, inlet(s) **26** being connected to elongated introduction means **30**, **32** respectively." (Col. 3, ll 12-15); "introduction of chemical hardening material via syringe" (Col. 2, ll 26-27); FIG. 3.
[23d] d) a valve integral with one of the plurality of cuffs for permitting entry of the inflation material from the means for inflating and thereafter sealing said cuff to prevent deflation.	**Samuels '851:** See disclosure in Claims Chart I above.
[24] 24. The apparatus of claim 22 further comprising means for securing an intraluminal medical device to the inner surfaces of the cuffs.	**Samuels '851:** See disclosure in Claims Chart I above.

3. Claims Chart III Summarizing the Presence of Support for Claim Phrase Elements/Identifiers in the Prior Art for Grounds 1-8

S '575	'851 Sam.	'024 Rog.	'088 Laz.	'117 Rhod.	'029 Lane	'767 Mill.	'745 Todd	'505 Siss.	'537 Holm.	'620 Pig.
1	✓	✓	✓	✓	✓				✓	✓
1a-1	✓	✓	✓	✓	✓				✓	✓
1a-2	✓	✓	✓		✓					
1a-3	✓	✓		✓	✓	✓	✓	✓		
1a-4	✓	✓	✓	✓	✓	✓	✓	✓		
1b	✓	✓	✓	✓	✓				✓	✓
1c	✓	✓	✓	✓						✓
2	✓	✓		✓	✓					
3		✓								
4		✓	✓	✓					✓	✓
5		✓	✓	✓					✓	✓
6	✓	✓	✓	✓	✓				✓	
7	✓			✓					✓	✓
8	✓									✓
9	✓		✓							
10	✓		✓	✓						
11	✓	✓	✓	✓					✓	✓
12	✓									
13	✓	✓	✓	✓	✓				✓	
14	✓	✓	✓	✓	✓				✓	✓
14a-1	✓	✓	✓	✓	✓				✓	✓
14a-2	✓	✓	✓		✓					
14a-3	✓	✓	✓	✓	✓				✓	✓
14a-4	✓	✓	✓	✓	✓				✓	✓
14b-1	✓	✓		✓	✓	✓	✓	✓		
14b-2	✓	✓	✓	✓	✓	✓	✓	✓	✓	
14c	✓	✓	✓	✓	✓				✓	✓
14d	✓	✓	✓		✓					✓
15	✓	✓		✓	✓					
16		✓	✓	✓					✓	✓
17		✓	✓						✓	✓
18	✓									✓
19	✓		✓							
20	✓		✓	✓						

21	✓	✓	✓	✓					✓	✓
22	✓									
23	✓								✓	
23a-1	✓								✓	
23a-2	✓								✓	
23a-3	✓								✓	
23b-1	✓				✓					
23b-2	✓								✓	
23c	✓								✓	
23d	✓									
24	✓									
S '575	**'851 Sam.**	**'024 Rog.**	**'088 Laz.**	**'117 Rhod.**	**'029 Lane**	**'767 Mill.**	**'745 Todd**	**'505 Siss.**	**'537 Holm.**	**'620 Pig.**

VII. Conclusion

For the above reasons, Petitioner respectfully requests institution of *inter partes* review of Claims 1-24, *i.e.*, all the claims of the Samuels '575 Patent.

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CERTIFICATE OF SERVICE

I hereby certify that on this 5th day of August, 2013, the foregoing PETITION FOR *INTER PARTES* REVIEW UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.1 *ET SEQ*., including Exhibits, were served pursuant to 37 C.F.R. §§ 42.6 and 42.105, via Federal Express®, next day delivery, on the following:

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