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Title of Invention:	DEVICE FOR ENDOVASCULAR AORTIC REPAIR
First Named Inventor/Applicant Name:	Ali Shahriari
Customer Number:	175373
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Edwards v. Aortic Innovations
U.S. Patent 11,389,310
Edwards Ex. 1046

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		426-2-19UTIL-20201130-PrelimAmend.pdf	973585	yes	25
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Multipart Description/PDF files in .zip description			
Document Description	Start	End	
Applicant Arguments/Remarks Made in an Amendment	5	25	
Claims	2	4	
Preliminary Amendment	1	1	
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**COMMUNICATION TO THE UNITED STATES PATENT AND TRADEMARK
OFFICE**

Application No.	:	17/096,253	Confirmation No.:	5047
Applicant	:	Aortic Innovations, LLC		
First Named Inventor	:	Ali Shahriari		
Filing Date	:	Nov 12, 2020		
TC/A.U.	:	3774		
Examiner	:	-		
Docket No.	:	426/2/19 UTIL		
Customer No.	:	175373		

Title of Invention: DEVICE FOR ENDOVASCULAR AORTIC REPAIR

Via EFS-Web

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRELIMINARY AMENDMENT

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 5 of this paper.

Amendments to the Claims:

The claims are amended as follows and will replace all previous versions and listings of claims:

Listing of Claims:

Claims 1-10 (Canceled)

11. (New) A valve assembly comprising:

an outer frame, wherein the outer frame is formed from a metallic material and defines an open cell configuration;

an inner frame that engages a prosthetic heart valve having prosthetic leaflets, wherein the inner frame includes a cylindrically extending inner graft covering extending at least partially radially outwardly of the prosthetic heart valve and radially inwardly of the outer frame for providing sealing to the prosthetic heart valve,

wherein the outer frame is secured to the inner graft covering by stitching at a proximal end of the outer frame;

an outer seal for preventing paravalvular leaks that begins at a proximal portion of the outer frame and extends over at least two rows of cells formed in the outer frame,

wherein the outer seal is attached to the outer frame,

wherein the outer seal is formed of outwardly extending fibers positioned externally to the outer frame,

wherein the outer seal is free of an outer graft covering between the fibers and the outer frame,

wherein the valve assembly has a radially compressed orientation and a radially expanded orientation,

wherein the valve assembly is balloon expandable and expansion of the valve assembly presses some of the fibers against native leaflets of the aorta of the patient.

12. (New) The valve assembly of claim 11, wherein the outer frame extends distally further than the prosthetic heart valve.

13. (New) The valve assembly of claim 11, wherein the outer frame is a singular, integral component.

14. (New) The valve assembly of claim 11, wherein the outer frame and the inner graft covering are attached by stitches at a distal and proximal portion of the inner graft covering.

15. (New) The valve assembly of claim 11, wherein the inner graft covering and the fibers are distinct elements.

16. (New) The valve assembly of claim 11, wherein the valve assembly is delivered endovascularly.

17. (New) The valve assembly of claim 11, wherein a seal is created between the inner frame and the outer frame.

18. (New) The valve assembly of claim 11, wherein a portion of the outer frame is uncovered by the graft covering and the outer seal.

19. (New) The valve assembly of claim 11, wherein a distal end of the outer frame extends distally beyond the prosthetic leaflets.

20. (New) The valve assembly of claim 11, wherein the graft covering extends beyond a proximal end of the outer frame and over the proximal end thereof to cover the proximal end of the outer frame.

21. (New) The valve assembly of claim 11, wherein the outwardly extending fibers extend outwardly to different positions relative to a centerline run through a longitudinal of the valve assembly.

22. (New) The valve assembly of claim 11, wherein the graft covering, outer seal, and prosthetic leaflets are radially overlapping.

REMARKS

Applicant submits the claims enclosed herewith as a preliminary amendment in this matter. Applicant is submitting relevant references known to Applicant. Applicant discusses a few of those references in detail herein.

The first independent claim recites:

*11. A transcatheter heart valve assembly comprising:
an outer frame, wherein the outer frame is formed from a metallic material and defines an open cell configuration;
an inner frame that engages a prosthetic heart valve having prosthetic leaflets, wherein the inner frame includes a cylindrically extending inner graft covering extending at least partially radially outwardly of the prosthetic heart valve and radially inwardly of the outer frame for providing sealing to the prosthetic heart valve,
wherein the outer frame is secured to the inner graft covering by stitching at a proximal end of the outer frame;
an outer seal for preventing paravalvular leaks that begins at a proximal portion of the outer frame and extends over at least two rows of cells formed in the outer frame,
wherein the outer seal is attached to the outer frame,
wherein the outer seal is formed of outwardly extending fibers positioned externally to the outer frame,
wherein the outer seal is free of an outer graft covering between the fibers and the outer frame,
wherein the valve assembly has a radially compressed orientation and a radially expanded orientation,
wherein the valve assembly is balloon expandable and expansion of the valve assembly presses some of the fibers against native leaflets of the aorta of the patient.*

This claim is well illustrated with reference to FIGS. 11 and 12 of the application as filed:

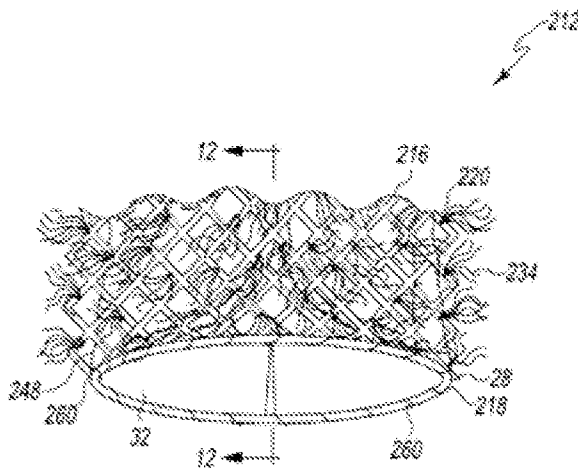


Fig. 11

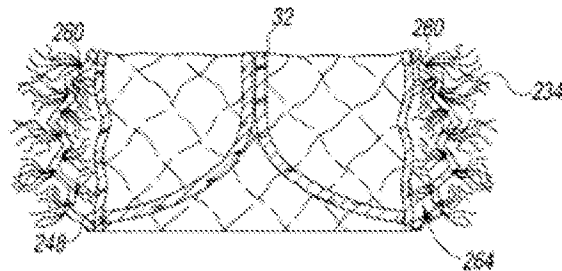


Fig. 12

Applicant notes that the claims recite a so-called negative limitation: “*wherein the outer seal is free of an outer graft covering between the fibers and the outer frame.*” MPEP 2173 is controlling on the use of support for negative limitations:

Any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See In re Johnson, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) (“[the] specification, having described the whole, necessarily described the part remaining.”). See also Ex parte Grasselli, 231 USPQ 393 (Bd. App. 1983), aff’d mem., 738 F.2d 453 (Fed. Cir. 1984). The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Note that a lack of literal basis in the specification for a negative limitation may not be sufficient to establish a prima facie case for lack of descriptive support. Ex parte Parks, 30 USPQ2d 1234, 1236 (Bd. Pat. App. & Inter. 1993).

Additionally, the Federal Circuit has clarified the standards for negative limitations as well. The Federal Circuit has held that a negative limitation has written description support when the specification “describes a reason to exclude the relevant limitation.” *Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344, 1351 (Fed. Cir. 2012). That standard is easily satisfied with the disclosure. Such written description support need not rise to the level of disclaimer. In fact, it is possible for the patentee to support both the inclusion and exclusion of the same material. The

specification discloses multiple embodiments of a heart valve, and some of the embodiments show a design with an outer graft covering, and some of the other embodiments show a design that is free of an outer graft covering. The inclusion of an embodiment that includes an outer graft covering, and an embodiment without an outer graft covering provides support for the negative limitations disclosed herein. The specification even states “It should be appreciated that in other embodiments the outer frame 216 may be covered with hydrogel or other sealing materials,” implying that alternate sealing materials, such as a non porous graft covering may or may not be provided.

The claims are directed towards an improved transcatheter aortic valve replacement (TAVR) that address paravalvular leaks (PVL). Namely, by having an inner frame that is a graft covering around the heart valve, sealing aspects are provided to the valve against the metallic outer frame. This helps to provide a seal around an inner facing surface of the metallic frame, as well as to protect at least portions of the valve leaflets from contact with the metal frame. The outer seal provides sealing between the outer frame and the patient’s anatomical wall, while avoiding problems associated with conventional TAVR devices that will be discussed further herein.

PROBLEMS WITH EXISTING TAVR DEVICES

TAVR devices have competing design forces at all times. The TAVR must maximize valve leaflet size, provide sealing characteristics to reduce PVL and PVR¹, yet, must maintain a small overall crimped profile as the compressed TAVR must be delivered endovascularly through an access artery and cross the native heart valve of the patient², maintain appropriate asymmetric foreshortening characteristics³, and maintain appropriate hoop stresses and forces so that undue pressure is not required to inflate the balloon for balloon expandable valves or for self-expansion for self-expanding valves, or underexpansion of the valve assembly can occur⁴.

US Patent Publication No. 20120123529 (“Levi”), which is discussed further herein, well describes this problem of crimp profile with respect to the inner skirt:

¹ <https://www.acc.org/latest-in-cardiology/articles/2017/02/02/08/25/transcatheter-management-of-paravalvular-leaks>

² <https://www.sciencedirect.com/science/article/pii/S2666084919304760>

³ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6551197/>

⁴ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5300953/>

[0066] Known fabric skirts comprise a weave of warp and weft fibers that extend perpendicular to each other and with one set of fibers extending perpendicularly to the upper and lower edges of the skirt. When the metal frame, to which the fabric skirt is secured, is radially compressed, the overall axial length of the frame increases. Unfortunately, a fabric skirt, which inherently has limited elasticity, cannot elongate along with the frame and therefore tends to deform the struts of the frame and prevents uniform crimping.

While this was in reference to the inner skirt, the same concerns are presented with an outer skirt where conformability to the native annulus is even more pronounced. Thus, it should be evident that a balloon expandable outer frame (which is thus subject to higher compressive forces) having an outer graft covering of sufficient height, along with an inner graft covering, presented significant engineering design challenges. Designing an outer seal that would effectively seal and limit PVL for a balloon expandable frame is thus desirable.

The issue with the outer seal is particularly relevant because paravalvular leaks and regurgitation are a persistent problem with TAVR. For example, a recent study found that the CoreValve prosthesis, one of the few available TAVR devices in the United States market, had moderate or severe PVR of 11.4% and 9.0% at 30 days. From the study involving 60 patients:

The primary efficacy endpoint was defined as the proportion of patients with less-than-mild prosthetic valve regurgitation at 30 days and amounted to 72.4%, with no patient showing evidence for moderate or severe regurgitation. Of the patients without a pacemaker at baseline, 11.8% required implantation of a permanent pacemaker within 30 days after TAVR. The mean transprosthetic gradient was low with 6.4 mm Hg as typical for a supra-annular valve design, though acknowledging that no patient requiring a 23-mm device was included. The pre-defined primary safety endpoints, all-cause mortality and disabling stroke at 30 days, amounted to 1.7% each in a patient population with a mean Society of Thoracic Surgeons score of 6.4%. Thirty-day rates of major vascular complications and life-threatening or disabling bleeding were 10.0% and 11.7%, respectively.

The presented data are promising and support the concept to mimic surgical-like outcomes as it relates to PVR by the addition of an external seal that compensates for incomplete stent-landing zone apposition...

<http://interventions.onlinejacc.org/content/jint/11/2/169.full.pdf>

From another study:

Moderate to severe regurgitation after TAVR confers a poor prognosis and is associated with an increased risk of all-cause mortality. Even mild PVL has been shown to have a negative impact on survival. Kodali et al reported on the outcomes of patients who underwent TAVR from the randomized cohorts of the PARTNER trial and continued access registries. Data were analyzed from a total of 2,434 patients. PVL was reported as mild in 38% and moderate/severe in 9.1% of patients after TAVR. There was no difference in 30-day mortality. Instead, the adverse effect was expressed later with a significant increase in 1-year all-cause and cardiac mortality and repeat hospitalization in those with worsening PVL.

<https://citoday.com/articles/2015-july-aug/managing-paravalvular-leaks-after-tavr>

Thus, as these studies show, PVL is a long-felt problem and a method of addressing them has been needed. Studies show high one year mortality and rehospitalization rates of 35% and 31% may be attributed to PVL, and reducing PVL will thus reduce mortality and rehospitalization rates. According to this study, an external seal helps to address PVL and PVR. Surgical valves, as will be discussed herein, did not traditionally have significant PVL concerns because the valve leaflets were removed from the patient, and a sealing ring or similar could be stitchably engaged with the aorta in an open heart procedure. However, a robust outer seal system on a TAVR presents problems with expansion forces, foreshortening, underexpansion, and crossing of the aorta. The claimed invention addresses these problems.

A LONG-FELT NEED EXISTED TO REDUCE PVL WHILE MAINTAINING SMALL VALVE PROFILE, AND MULTIPLE ATTEMPTS TO DO SO WERE NOT LEADING TOWARDS THE CLAIMED INVENTION

There were multiple TAVRs available in 2012 at the effective filing date of this application, however, none of TAVRs known to Applicant taught a fiber outer seal. As an example, consider the following image depicting one example of the state of the art for TAVRs in 2012:

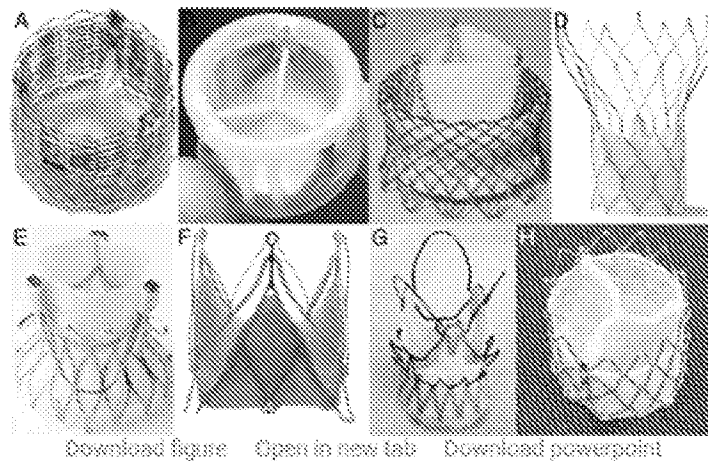


Figure 4
Valves Undergoing Early Evaluation

(A) Lotus (Boston Scientific Inc., Natick, Massachusetts), (B) Direct Flow (Direct Flow Medical Inc., Santa Rosa, California), (C) HLT (Braeco Inc., Princeton, New Jersey), (D) Portico (St. Jude Medical Inc., St. Paul, Minnesota), (E) Engager (Medtronic Inc., Minneapolis Minnesota), (F) JenaClip (JenaValve Inc., Munich, Germany), (G) Acurate valve (Symetis Inc., Ecublens, Switzerland), and (H) Inovare (Braille Biomedica Inc., São José do Rio Preto, Brazil) valves.

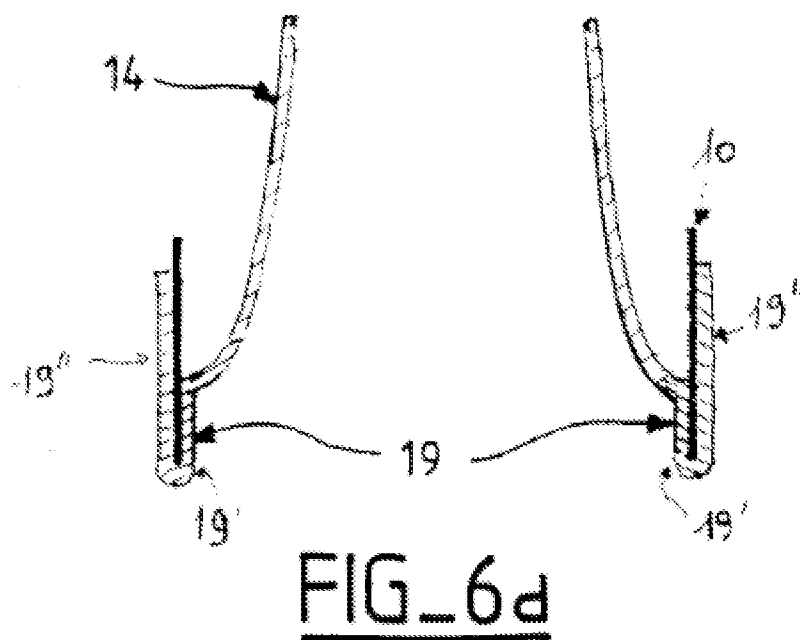
<https://pubmed.ncbi.nlm.nih.gov/22749306/>

In this image, there are eight (8) distinct transcatheter valves shown. Four (4) of the eight (8) appear to teach an outer seal, and several of the ones that do not teach an outer seal had later variations of their product lines that do teach an outer seal. None of them teach a fiber based outer seal. Much of the art taught an outer seal that was largely non-compliant in structure, and sealed by having an initial density or non-porosity conducive to sealing. None of the seals worked by having a group of fibers that would work to seal against PVL once the fibers were compressed from implantation.

A DISCUSSION OF SOME OF THE PRIOR ART FOLLOWS:

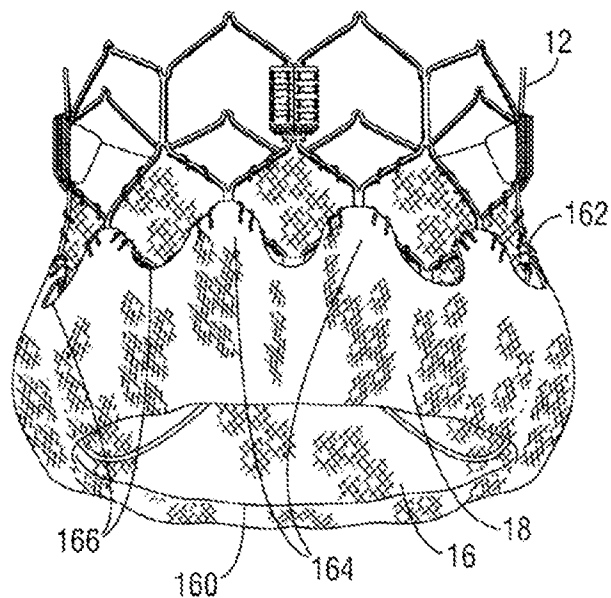
TRANSCATHETER VALVE TECHNOLOGY

An example of a transcatheter valve having an inner and outer seal is shown in at least WO98/29057 (“Cribier”). See for example FIG. 6D that shows a cover extending from an inner surface to an outer surface of the stent frame.



Similarly, US Patent Publication No. 20120123529 (“Levi”) appears to teach an inner and outer seal in FIG. 42.

FIG. 42



WO2006/005015 (“Spenser”) appears to teach a thick band with fibers emanating therefrom in FIG. 22, however, there is no graft forming the inner frame, thus the inner sealing is missing. FIG. 22 is reproduced below:

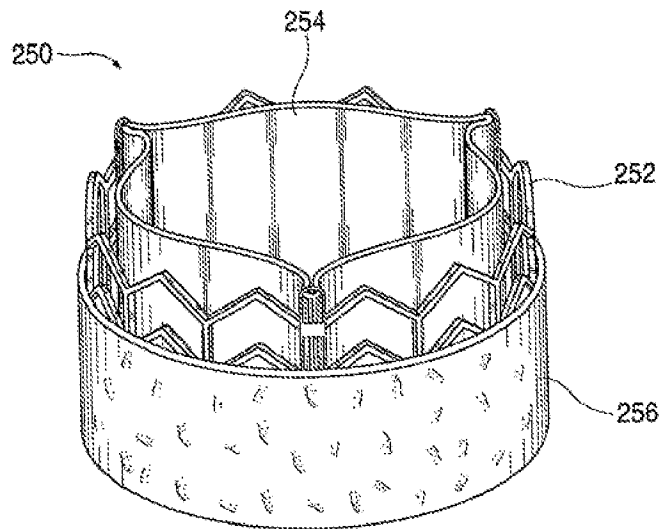


FIG. 22

US Patent No. 7381219 (“Salaheih”) teaches a repositionable TAVR with sacs filled by hydrogel or similar on an exterior of the TAVR for sealing the TAVR:

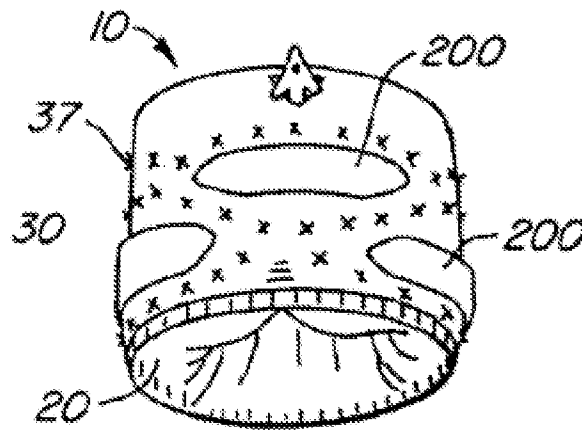
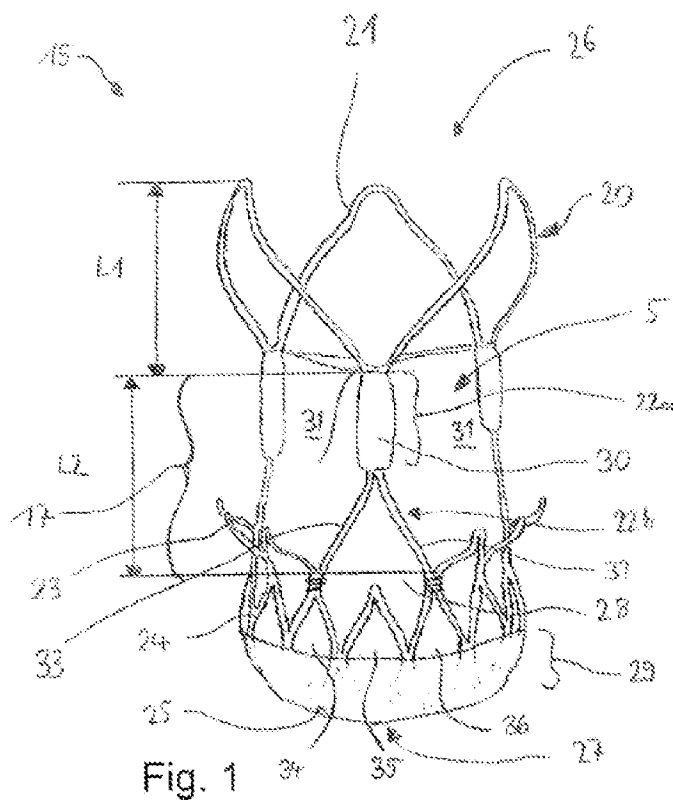


FIG. 15A

US Patent No. 9333075 (“Delaloye”) teaches a TAVR with an outer seal at a proximal end.



STENT GRAFT TECHNOLOGY

Various stent grafts have also been developed that include one or more seals. US Patent Publication No. 2004/0256759 ("Hartley") teaches a velour band at a distal end of the stent graft.

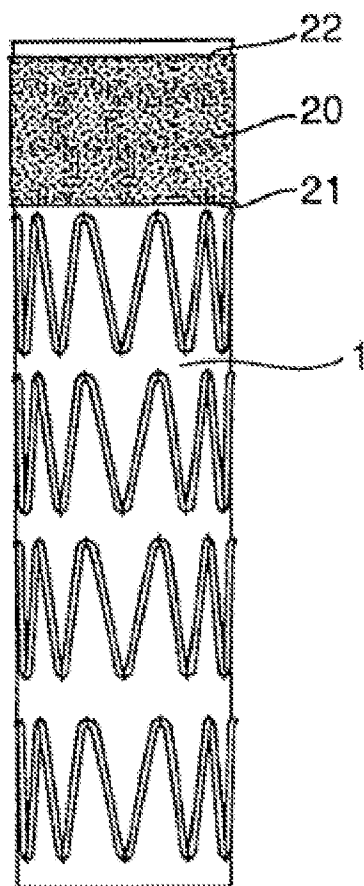


Fig 2

Similarly, US Patent No. 7,921,678 (“Norris”) teaches a stent graft with loops of outwardly extending material.

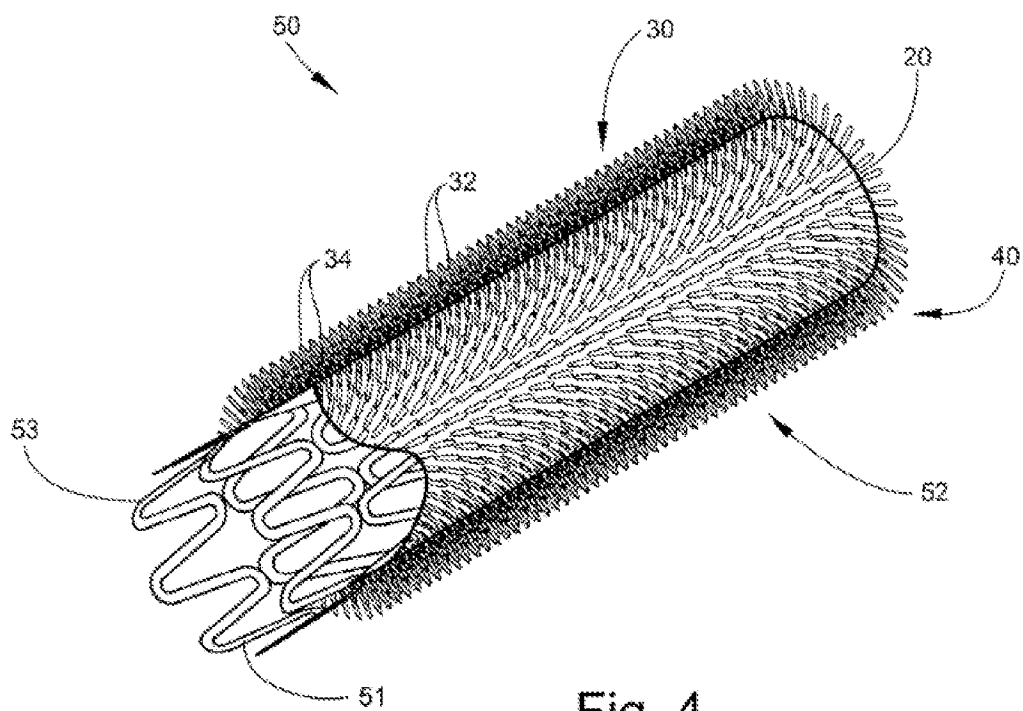
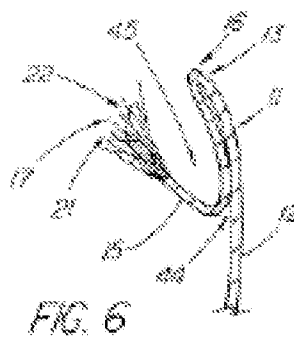
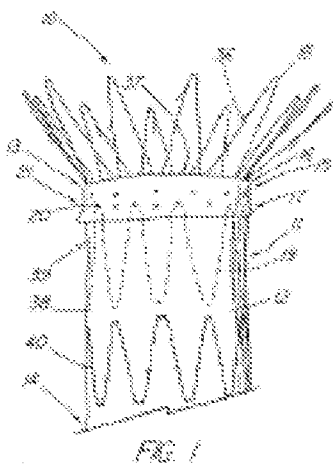
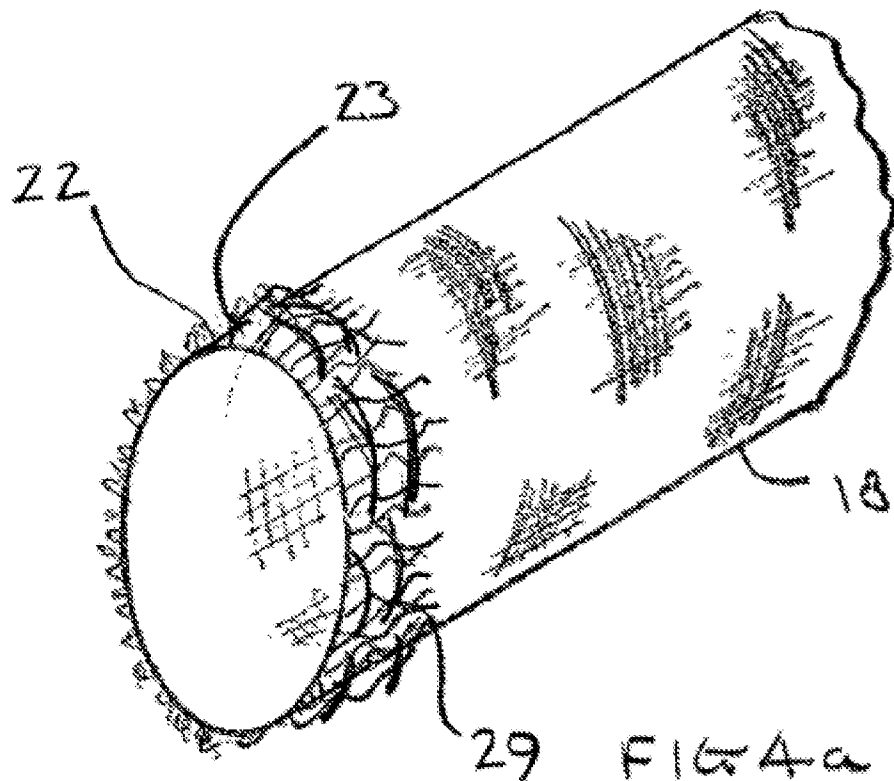


Fig. 4

US Patent Publication No. 2004/0082989 (“Cook”) teaches a cuff portion with a frayed portion 22:

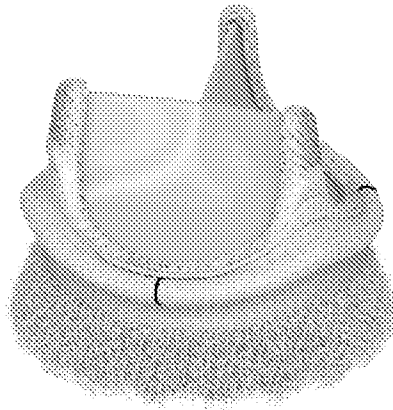


US Patent Publication No. US 2002/0052649 ("Greenhalgh") teaches a stent graft with fibers emanating therefrom:



SURGICAL VALVES

The non-patent literature of Intuity does appear to teach an external seal that includes fibers. Intuity appears to show a surgical valve from 2011 that has a plush outer seal similar to the valve shown in US Patent No. 9,370,418, which has been discussed in prosecution of Application No. 16/808,137 in front of Examiner Shipmon and that is related to this pending application.



This surgical valve would appear to teach a seal that seals below the leaflets, and not against native valve leaflets of the patient. In fact, typically the native leaflets are surgically removed during surgical heart valve replacement. Additionally, because a surgical valve does not have the access issues associated with transcatheter valves, the increased overall profile of a surgical valve such as Intuity is not as problematic.

IMPROVEMENTS ASSOCIATED WITH CLAIMED INVENTION

The combination of a balloon expandable transcatheter stent valve with an outer seal with outwardly extending fibers, along with the other limitations found in the claims, presented an improvement over the prior art, with particular reference to the unexpected results of products covered by claims in prosecution of the '137 Application (Now USPN 10,792,172). Applicant submits that it was not obvious to combine the seal found in the references submitted with the information disclosure statement with the TAVR technology of record to seal against the native leaflets of the patient with a fiber outer seal. The reasons for this are discussed herein.

The native annulus of a patient is relatively small in diameter, and with a diseased aorta suffering from stenosis, the diameter limitations become even more pronounced. At the position where the native leaflets extending into the ascending aorta, sizing a valve is difficult, and crossing the valve without pre-dilation has proven challenging. Placing a seal on an inner surface of the outer frame, along with a seal on an outer surface of the outer frame thus undesirably increases the overall valve profile. Additionally, the compressed assembly must fit within a sheath or catheter for delivery into the patient through an access artery and cross the

aortic valve. For this reason, much of the prior art where an inner and outer seal is disclosed, teaches a relatively thin graft material for both the inner seal and outer seal. (See, for example, Cribier and Levi discussed herein). When there was an outer seal, the seal also often had a relatively short height so that the sealing aspects would be below the native leaflets or extending into crevices created by the native leaflets, but not radially overlapping with the leaflets at a most narrow spot of the ascending aorta (see again Cribier, and Levi with the billowing outer graft). On devices that had an outer seal of more sufficient thickness, the device often did not have an inner seal (see, for example, Spenser); this was likely due to increased valve profile, and increased hoop forces that made expansion of the compressed valve more difficult and susceptible to underexpansion, or undesirable valve crimp profile.

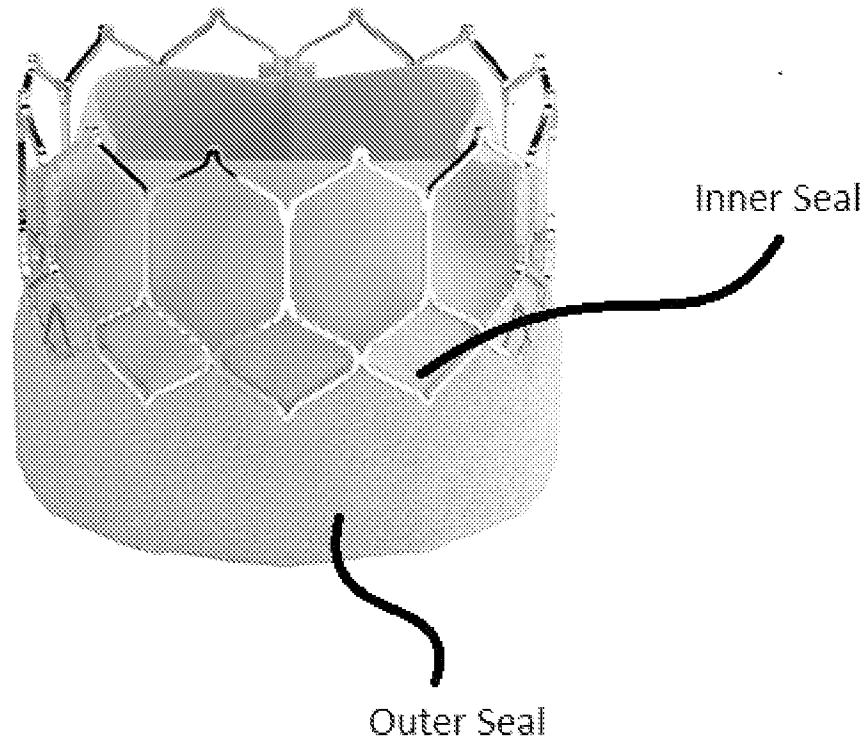
The Intuity valve is of such high crossing profile that it is implanted without a sheath and through a conventional surgical approach after the native valve leaflets have been surgically removed to create space. The Intuity valve is stitched to the annulus to create a seal.

Additionally, placing outer seal bands as disclosed by Spencer, Cribier and Levi, creates significant technical limitations in the functionality of the TAVR device during loading of the device into a sheath and deployment of the devices *in vivo*. These disclosures show balloon-expandable stent frames. A balloon-expandable frame has a dynamic length, where in an undeployed crimped state, the frame is taller and gradually shortens as the frame is ballooned and expanded to be placed in its final *in vivo* position. Applicant submits that the density of this outer seal band (Spencer, Cribier, and Levi) restricts the necessary foreshortening of the stent frame during deployment *in vivo* and can cause PVL, migration, under-deployment and malfunction of the valve leaflets. Thus when the Levi valve was created, significant laxity was designed and allowed in the short outer seal to accommodate the foreshortening of the stent frame. Due to these sizing issues, despite the availability of an outer seal having outwardly extending fibers in the stent graft, heart valves, and other stent materials, a TAVR with an inner seal and an outer seal where the outer seal included outwardly extending fibers from a graft covering, along with other limitations found in the claims, was not developed.

A recent study compared a valve similar to that shown in Levi and with a valve termed the Sapien 3 Ultra that appears to be covered by the claimed invention. In the study, the Levi invention had mild PVL in 22.3% of cases, whereas, the Ultra had in only 7.2%.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5387215/>. The Sapien 3 Ultra device includes

an inner frame that is a graft and an outer seal that includes outwardly extending fibers. The added benefits of outwardly extending fibers in this product allowed for a much reduced crossing profile, placement of an additional inner seal, and a much improved external seal as clinically shown. A representative image of the Sapien 3 Ultra product is shown below:



Applicant thus submits that the claimed invention represents an improvement over the prior art of record in reducing PVL, while maintaining a sufficiently small enough profile to be implanted endovascularly without concerns associated of foreshortening and under-deployment typically expected of a device having an inner and outer seal where the outer seal has significant dimensionality.

The fibers increase the surface area of the outer seal, which encourages tissue ingrowth to reduce PVL and increase thrombosis. This also increases the stability of the TAVR in the aorta so that the TAVR does not migrate within the aorta. These advantages are provided in a TAVR that still maintains good compressibility while reducing the overall crimp profile of the TAVR as compared to a modified TAVR with a large thickness outer seal.

Applicant thus submits that the invention claimed herein is patentable over the prior art of record.

THE CLAIMED IMPROVEMENT OF A SEALING MATERIAL INCLUDING A PLURALITY OF OUTWARDLY EXTENDING FIBERS IS NOT OBVIOUS OVER THE PRIOR ART OF RECORD BECAUSE THE VALVE PROFILE WOULD BE UNSATISFACTORILY INCREASED IF ONE WERE TO COMBINE THE OUTER SEAL OF SPENSER AND TAVR VALVES HAVING AN INNER SEAL

As discussed, maintaining a small overall valve profile is crucial for valve performance and deployability. However, the seal of Spenser appears to be relatively thick in construction, including a graft covering or sleeve with fibers extending from the sleeve. Foreshortening of the Spenser seal would likely be more problematic as well given the construction and would not only significantly increase the crossing profile, but also restrict the expansion of the balloon-expanding frame and result in underdeployment and valve malfunction. Spenser discloses a seal having a thickness of up to 5 mm, which would increase overall valve profile by up to 10 mm. Valve designs are typically in the 20 to 30 mm diameter range, and thus a 10 mm increase in diameter size, in addition to adding an inner graft covering as claimed, would be undesirable. Furthermore, addition of a seal of such significant thickness would increase the inflation pressures required of the balloon assembly, where rupture of the balloon has already proven problematic.

Furthermore, Spenser already teaches a method of addressing PVL, namely, seal 256. (“To reduce or prevent paravalvular leakage, a layer of compressible material 256 is disposed along an outer surface of the stent structure 252.”) [0145]. When the prior art already teaches a solution to the problem, then one of ordinary skill would not look to further modify the prior art by adding an inner seal, to address the problem that the prior art has already addressed. Additionally, the Spenser device, as modified to meet the claimed invention, may have problems associated with crimp profile, and Spenser appears to include an outer graft covering between the fibers and the outer frame, which is a claimed negative limitation. Finally, Spenser is not modifiable to be free of an outer graft covering, as such modification would have no structure for the fibers to attach to since the fibers emanate from compressible material 256.

**ONE WOULD NOT LOOK TO STENT GRAFT SEALS TO MODIFY A TAVR SUCH
AS LEVI, CRIBIER, OR SPENSER**

Some of the stent graft references disclose outwardly extending fibers. One of ordinary skill would not look to stent graft technology because the stent grafts require a much greater seal area for treating aneurysms or dissections. See for example, Hartley and Norris. The stent grafts are self-expanding with a larger profile and reduced hoop stress. The structure of stent grafts is such that they may not be able to resist the recoil forces of the stenosed aortic valve, leading to underdeployment of the stent graft. Stent grafts due to the design of their stent skeleton do not significantly foreshorten and thus a less compliant sheet of velour or base band with fibers will not restrict the expansion of the stent graft in its intended use location, namely healthy aortic necks of aneurysms; this is due to the rings of stents that are spaced-apart, as compared to the open cell, interconnected structure of the claimed invention.

For successful use of a stent graft, the proximal section of the stent graft should be placed in relatively healthy aortic segments. The use of stent grafts in heavily calcified aortic sections has generally been undesirable and the crossing profile does not pose the similar challenges seen in treatment of aortic valve stenosis, thus less compliant thicker bands may be used externally on the stent grafts used for treatment of aneurysms or dissection.

TAVRs have a different frame design as compared to stent grafts where the TAVR has an interconnected frame structure. The structure of the TAVR is such that it can resist the recoil forces of the stenosed aortic valve and foreshortening is a function of the deployed state of the valve after balloon expansion. Thus the requirements for external seals are much different than those for stent grafts. Due to the fact that a stent graft will not further carry an internal component such as prosthetic leaflets like a TAVR, and the profile considerations of a stent graft are not as pronounced as a TAVR.

Additionally, and importantly, the stent graft technology generally appears to teach a graft covering on the outside of the metal stent frame, and the fibers extend from the graft covering. The claimed invention recites that the outer seal is free of an outer graft covering.

External seal bands such as those disclosed by Spencer will significantly add to the profile of the TAVR and prevent smooth crossing of the stenosed aortic valve, thus an inner seal is not likely designed for the Spencer valve as it will add further to the crossing profile.

Similarly, a band of velour or dense band additional fibers as disclosed by Hartley would not likely be used together with the Spencer or Cribier valve because it will restrict the expansion and the foreshortening of the TAVR during balloon expansion and result in underdeployment of the TAVR resulting in PVL, migration and valve malfunction.

Finally, TAVRs have much more limited axial length for proper placement relative to the coronaries to avoid inadvertent covering of the coronaries. The claimed invention allows significant expansion of the TAVR without restricting the valve opening or stent foreshortening in addition to allowing for a lower profile of the TAVR making it possible to use an inner graft frame that further reduces leaks and protects the prosthetic valve leaflets from hitting the metallic frame.

**CLAIM 11 RECITES THAT THE FIBERS COVER AT LEAST TWO
CIRCUMFERENTIALLY EXTENDING ROWS OF OPEN CELLS FORMED IN THE
OUTER FRAME**

The limitation of the fibers covering at least two rows of open cells provides an improvement over the prior art of record because this provides a heightened seal that allows for sealing below the native leaflets and at the native leaflets. Additionally, by having at least two rows of open cells being covered by fibers allows for greater compliance of the stent frame and seal, thus further reducing PVL. Furthermore, Applicant submits that this combination of claimed features provides an increased landing zone for implantation of the stent assembly and an increased surface area for engagement with emboli that is maintained in place instead of otherwise allowed to flow into the arch and possibly causing stroke, all aspects that decrease post-surgical complications.

**NEW CLAIM 18 RECITES THAT A PORTION OF OUTER FRAME IS UNCOVERED
BY THE GRAFT COVERING AND THE OUTER SEAL**

This advantageously provides for the outer frame to provide an area for the sealing material, and another portion of the outer frame where the inner graft covering and outer seal does not extend to. This allows for blood flow through a portion of the stent frame from the coronary arteries, while providing for a sealing material that extends at least a majority of the

height of the first open cell portion. The sufficient height of the outer seal provides an increased landing zone area and ability to seal against the leaflets of the patient

NEW CLAIM 20 RECITES THE GRAFT COVERING EXTENDS BEYOND A PROXIMAL END OF THE OUTER FRAME AND OVER THE PROXIMAL END THEREOF TO COVER THE PROXIMAL END OF THE OUTER FRAME.

New claim 20 advantageously provides that the graft covering extends beyond the proximal end of the outer frame. This seals the proximal end of the TAVR, and also provides a smooth leading edge for translation of the TAVR within a catheter deployment system.

NEW CLAIM 21 RECITES THAT THE FIBERS OF THE PLURALITY OF FIBERS EXTEND OUTWARDLY TO DIFFERENT POSITIONS RELATIVE TO A CENTER LINE OF THE VALVE ASSEMBLY ALONG A LENGTH THEREOF

This is well illustrated with FIG. 12:

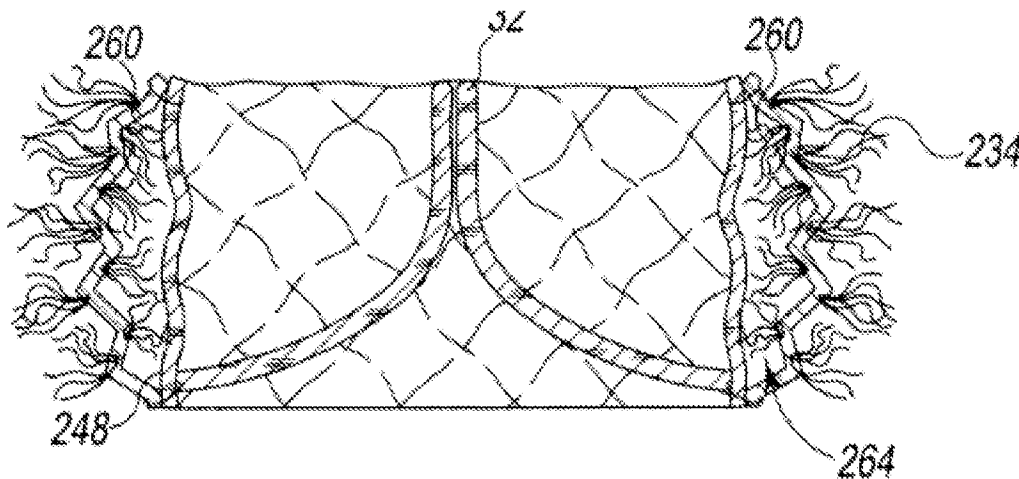


Fig. 12

This advantageously creates a diversity in engagement and forces applied to the fibers when sealing against the annulus and leaflets, creating a diversification in opportunities to thrombose the valve assembly to seal the assembly and reduce or eliminate PVL.

NEW CLAIM 22 RECITES THAT THE GRAFT COVERING, PROSTHETIC HEART VALVE, AND OUTER SEAL ARE RADially OVERLAPPING

This advantageously provides that the sealing components (graft covering and outer seal) are radially overlapping with the prosthetic heart valve. The claimed combination creates sealing where the prosthetic heart valve is positioned, and where the valve may be more likely to have PVL.

DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any otherwise unpaid fees associated with the filing of this correspondence to Deposit Account No. **50-6191**.

Respectfully submitted,

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