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EV374587856US (Express Mail Label)

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Applicant:	Benjamin Spenser et al.
Serial No:	To Be Assigned
Filing Date:	June 30, 2004, herewith
For:	Paravalvular Leak Detection, Sealing, & Prevention
Enclosures:	(1) Utility Patent Application Transmittal (page); (2) Specification (40 pages); (3) Drawings (20 sheets); (4) NonPublication Request (1 page); (5) UNExecuted Declaration (3 pages); (6) UNExecuted POA (3 pages); (7) Acknowledgement Postcard.

PTO/SB/05 (08-03)
Approved for use through 07/31/2006. OMB 0651-0032
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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	501015.20517
First Inventor	Benjamin Spenser
Title	Paravalvular Leak Detection ...
Express Mail Label No.	EV 374587856 US

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

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1. ☐ Fee Transmittal Form (e.g., PTO/SB/17)
(Submit an original and a duplicate for fee processing)
2. ☐ Applicant claims small entity status. See 37 CFR 1.27.
3. ☑ Specification [*Total Pages* 40]
(preferred arrangement set forth below)
- Descriptive title of the invention
- Cross Reference to Related Applications
- Statement Regarding Fed sponsored R & D
- Reference to sequence listing, a table, or a computer program listing appendix
- Background of the Invention
- Brief Summary of the Invention
- Brief Description of the Drawings *(if filed)*
- Detailed Description
- Claim(s)
- Abstract of the Disclosure

4. ☑ Drawing(s) (*35 U.S.C. 113*) [*Total Sheets* _____]
5. Oath or Declaration [*Total Sheets* _____]
a. ☑ Newly executed (original or copy) UNExecuted
b. ☐ Copy from a prior application (37 CFR 1.63(d))
(for continuation/divisional with Box 18 completed)
i. ☐ DELETION OF INVENTOR(S)
Signed statement attached deleting inventor(s) name in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
6. ☐ Application Data Sheet. See 37 CFR 1.76
7. ☐ CD-ROM or CD-R in duplicate, large table or Computer Program *(Appendix)*
8. Nucleotide and/or Amino Acid Sequence Submission *(if applicable, all necessary)*
a. ☐ Computer Readable Form (CRF)
b. Specification Sequence Listing on:
i. ☐ CD-ROM or CD-R (2 copies); or
ii. ☐ Paper
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ACCOMPANYING APPLICATION PARTS

9. ☐ Assignment Papers (cover sheet & document(s))
10. ☐ 37 CFR 3.73(b) Statement *(when there is an assignee)* ☑ Power of Attorney UNExecuted
11. ☐ English Translation Document *(if applicable)*
12. ☐ Information Disclosure Statement (IDS)/PTO-1449 ☐ Copies of IDS Citations
13. ☐ Preliminary Amendment
14. ☑ Return Receipt Postcard (MPEP 503) *(Should be specifically itemized)*
15. ☐ Certified Copy of Priority Document(s) *(if foreign priority is claimed)*
16. ☑ Nonpublication Request under 35 U.S.C. 122 (b)(2)(B)(i). Applicant must attach form PTO/SB/35 or its equivalent.
17. ☐ Other: .....

18. If a CONTINUING APPLICATION, *check appropriate box, and supply the requisite information below and in the first sentence of the specification following the title, or in an Application Data Sheet under 37 CFR 1.76:*

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.: .....

Prior application information: *Examiner* _____ *Art Unit:* _____

For CONTINUATION OF DIVISIONAL APPS only; The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

19. CORRESPONDENCE ADDRESS

☑ Customer Number: 30452 *OR* ☐ Correspondence address below

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Name (Print/Type)	William H. Dippert	*Registration No. (Attorney/Agent)*	26,723
Signature	William H. Dippert	*Date*	June 30,2004

This collection of information is required by 37 CFR 1.53(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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NONPUBLICATION REQUEST UNDER 35 U.S.C. 122(b)(2)(B)(i)

First Named Inventor	Benjamin Spenser
Title	Paravalvular Leak Detection, Sealing, And ...
Attorney Docket Number	501015.20517

I hereby certify that the invention disclosed in the attached application **has not and will not be** the subject of an application filed in another country, or under a multilateral agreement, that requires publication at eighteen months after filing.

I hereby request that the attached application not be published under 35 U.S.C. 122(b).

June 30, 2004
Date


Signature

949-250-6878
Telephone number

William H. Dippert
Registration No. 26,723
for Christopher James

This request must be signed in compliance with 37 CFR 1.33(b) and submitted with the application **upon filing.**

Applicant may rescind this nonpublication request at any time. If applicant rescinds a request that an application not be published under 35 U.S.C. 122(b), the application will be scheduled for publication at eighteen months from the earliest claimed filing date for which a benefit is claimed.

If applicant subsequently files an application directed to the invention disclosed in the attached application in another country, or under a multilateral international agreement, that requires publication of applications eighteen months after filing, the applicant **must** notify the United States Patent and Trademark Office of such filing within forty-five (45) days after the date of the filing of such foreign or international application. **Failure to do so will result in abandonment of this application (35 U.S.C. 122(b)(2)(B)(iii)).**

PARAVALVULAR LEAK DETECTION, SEALING, AND PREVENTION

FIELD OF THE INVENTION

[0001] The present invention relates to implantable devices. More particularly it relates to the prevention, detection, and repair of paravalvular leaks around cardiac valve prostheses.

BACKGROUND OF THE INVENTION

[0002] Cardiac valve implantation is well known in the art. Less well addressed is how to detect possible leaks between the valve and surrounding blood vessel, how to seal such leaks, or how to design the valve such that it automatically seals the leaks.

[0003] Machiraju in U.S. Patent No 5,554,184, entitled "HEART VALVE ", describes a heart valve and a technique for effecting valve replacement or repair, which partially or completely replaces the mitral (or tricuspid) valve with an autologous graft from the pericardium, fascia lata or even the dura mater, or a bovine or porcine pericardial or other synthetic sheet material equivalent thereof, preferably in a configuration which substantially restores the original anatomy of the heart, including chordae tendineae attached to adjacent papillary muscles of the heart. Most preferably, a section of the patient's pericardium is cut to a shape including two leaflets, with each leaflet having a trabeculated tier of chordae tendineae terminating in a spear-shaped tab. The two leaflets are cut out as a single unit, and the two far ends are sutured together to yield a bileaflet valve having appended chordae and tabs.

[0004] Machiraju does not address leaks that can occur around the implanted valve.

[0005] Schreck in U.S. Patent No. 6,454,799, entitled, "MINIMALLY-INVASIVE HEART VALVES AND METHODS OF USE", describes expandable heart valves for minimally invasive valve replacement surgeries. In a first embodiment, an expandable pre-assembled heart valve includes a plastically-expandable annular base having a plurality of upstanding commissure posts. A tubular flexible member including a prosthetic section and a fabric section is provided, with the prosthetic section being connected to the commissure posts and defining leaflets therebetween, and the fabric section being attached to the annular base. In a second embodiment, an expandable heart valve includes an annular tissue-engaging base and a subassembly having an elastic wireform and a plurality of leaflets connected thereto. The annular base and subassembly are separately stored and connected just prior to delivery to the host annulus. Preferably the leaflet subassembly is stored in its relaxed configuration to avoid deformation of the leaflets. The expandable heart valves may be implanted using a balloon catheter. Preferably the leaflets of the heart valves are secured to the commissure regions of the expandable stents using a clamping arrangement to reduce stress.

[0006] Schreck also does not address leaks that can occur around the implanted valve.

[0007] Amplatz in U.S. Patent No. 6,638,257, entitled, "INTRAVASCULAR FLOW RESTRICTOR," describes an intravascular flow restrictor that comprises a braided tubular structure designed to be placed in the main pulmonary artery for limiting blood pressure in the lungs. The braided structure is designed to be collapsed for placement in a delivery catheter, but when it is ejected from the delivery catheter, it assumes a substantially larger diameter disk shaped device having one or more longitudinal channels or passways therethrough.

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