

(12) United States Patent Schreck

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(54) MINIMALLY-INVASIVE HEART VALVES AND METHODS OF USE

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Field of Search 623/2.1, 2.14,

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(56)**References Cited**

U.S. PATENT DOCUMENTS

| 3,755,823 A | * 9/1973 | Hancock 623/2.1 |
|-------------|----------|-----------------|
| 3,839,741 A | 10/1974 | Haller |
| 4,056,854 A | 11/1977 | Boretos et al. |
| 4,084,268 A | 4/1978 | |
| 4,477,930 A | 10/1984 | Totten et al. |
| 4,506,394 A | 3/1985 | Bedard |
| 4,592,340 A | 6/1986 | Boyles |
| 4,960,424 A | 10/1990 | Grooters |
| 4,994,077 A | 2/1991 | Dobben |
| 5,067,957 A | 11/1991 | Jervis |
| 5,163,953 A | 11/1992 | Vince |
| 5,332,402 A | 7/1994 | Teitelbaum |
| 5,370,685 A | 12/1994 | Stevens |
| 5,397,351 A | 3/1995 | Pavenik et al. |
| 5,411,552 A | 5/1995 | Andersen et al. |
| 5,486,193 A | 1/1996 | Bourne et al. |
| 5,489,296 A | 2/1996 | Love et al. |
| 5,531,785 A | 7/1996 | Love et al. |
| 5,545,209 A | 8/1996 | Roberts et al. |
| 5,545,214 A | 8/1996 | Stevens |
| 5,549,665 A | * 8/1996 | Vesely 623/2.1 |
| 5,554,185 A | 9/1996 | Block et al. |

| 5,571,174 A | 11/1996 | Love et al. |
|-------------|---------|-------------|
| 5.582.607 A | 12/1996 | Lackman |

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

| DE | 4316971 A1 | 5/1993 |
|----|------------|--------|
| EP | 0103546 B1 | 4/1988 |
| EP | 0362113 B1 | 4/1993 |

(List continued on next page.)

OTHER PUBLICATIONS

Lane et al., Pub. No. US 2002/0026238 A1, Pub Date Feb. 28, 2002, application 09/982,609.*

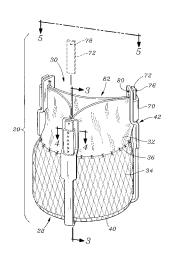
(List continued on next page.)

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(57)**ABSTRACT**

Expandable heart valves for minimally invasive valve replacement surgeries are disclosed. In a first embodiment, an expandable pre-assembled heart valve includes a plastically-expandable annular base having 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.

20 Claims, 10 Drawing Sheets





| U.S. PATENT DOCUMENTS | | | | |
|-----------------------|------------|---|---------|-----------------------|
| 5,607,465 | Α | | 3/1997 | Camilli |
| 5,612,885 | Α | * | 3/1997 | Love 623/2.1 |
| 5,669,919 | Α | | 9/1997 | Sanders et al. |
| 5,674,279 | Α | | 10/1997 | Wright et al. |
| 5,682,906 | Α | | 11/1997 | Sterman et al. |
| 5,695,515 | Α | | 12/1997 | Orejola |
| 5,716,370 | Α | | 2/1998 | Williamson, IV et al. |
| 5,716,399 | Α | | 2/1998 | Love |
| 5,716,417 | Α | * | 2/1998 | Girard 623/2.1 |
| 5,728,153 | Α | | 3/1998 | Menkis et al. |
| 5,824,064 | Α | | 10/1998 | Taheri |
| 5,840,081 | Α | | 11/1998 | Andersen et al. |
| 5,855,601 | Α | | 1/1999 | Bessler et al. |
| 5,855,603 | A | | 1/1999 | Reif |
| 5,928,281 | Α | * | 7/1999 | Huynh 623/2.1 |
| 5,935,163 | Α | * | 8/1999 | Gabbay 623/2.1 |
| 5,957,949 | Α | | 9/1999 | Leonhardt et al. |
| 5,980,570 | Α | | 11/1999 | Simpson |
| 5,984,959 | Α | | 11/1999 | Robertson et al. |
| 6,074,418 | Α | | 6/2000 | Buchanan et al. |
| 6,092,529 | Α | * | 7/2000 | Cox 623/2.11 |
| 6,264,691 | B1 | * | 6/2001 | Gabbay 623/2.14 |
| 6,336,937 | | * | 1/2002 | Vonesh et al 623/1.13 |
| 6,338,740 | B1 | * | 1/2002 | Carpentier 623/2.13 |
| 6,350,282 | | * | 2/2002 | Eberhardt 623/2.13 |
| 2001/0002445 | A 1 | | 5/2001 | Vesely |
| 2001/0007956 | A1 | | 7/2001 | Letac et al. |
| 2001/0021872 | A 1 | | 9/2001 | Bailey et al. |

FOREIGN PATENT DOCUMENTS

| EP | 0532678 B1 | 5/1996 |
|----|--------------|---------|
| EP | 0804911 A2 | 11/1997 |
| EP | 0850607 A1 | 7/1998 |
| ED | 1 057 460 A1 | 12/2000 |

| 1 088 529 A2 | 4/2001 |
|--------------|---|
| 1621912 A1 | 2/1989 |
| WO 96/19159 | 6/1996 |
| WO 96/40006 | 12/1996 |
| WO 97/09947 | 3/1997 |
| WO 97/09949 | 3/1997 |
| WO 97/46177 | 12/1997 |
| WO 99/30646 | 6/1999 |
| WO 99/33414 | 7/1999 |
| WO 99/53869 | 10/1999 |
| WO 99/56665 | 11/1999 |
| 00/41652 | 7/2000 |
| 00/44313 | 8/2000 |
| 00/45874 | 8/2000 |
| 00/47139 | 8/2000 |
| 00/48533 | 8/2000 |
| 01/52775 A1 | 7/2001 |
| 01/54625 A1 | 8/2001 |
| 01/56512 A1 | 8/2001 |
| | 1621912 A1 WO 96/19159 WO 96/40006 WO 97/09947 WO 97/09949 WO 97/46177 WO 99/30646 WO 99/33414 WO 99/53869 WO 99/56665 00/41652 00/44313 00/45874 00/47139 00/48533 01/52775 A1 01/54625 A1 |

OTHER PUBLICATIONS

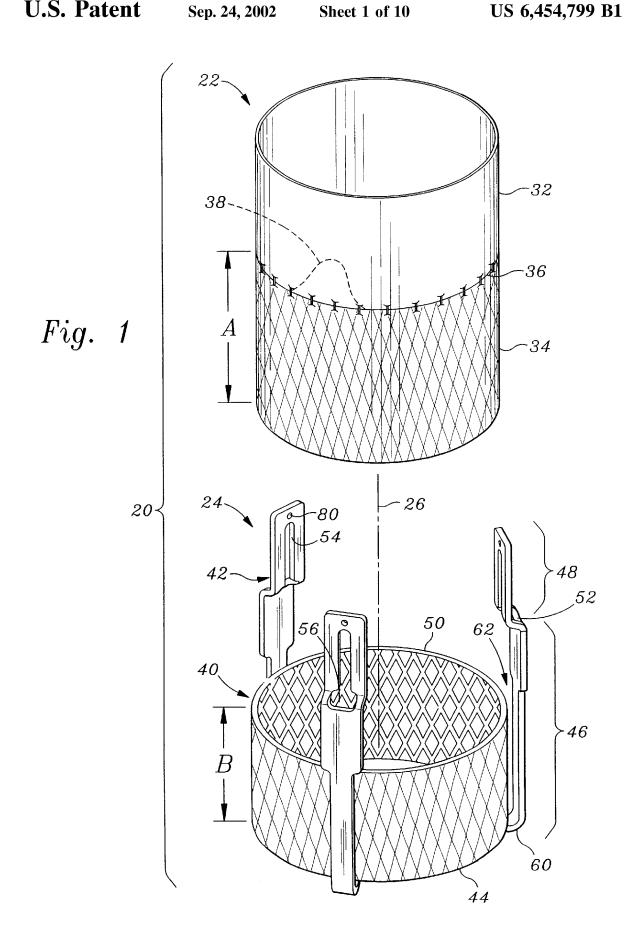
Ratner et al., Biomaterials Science, An Introduction to Materials in Medicine, Academic Press, 1996, p. 289.* Grismer, et al.; A Suture Holder and Separator Attachment to the Starr–Edwards Prosthetic Valve Holders, Surgery, Gynecology & Obstetrics, pp. 583–584, Mar. 1965.

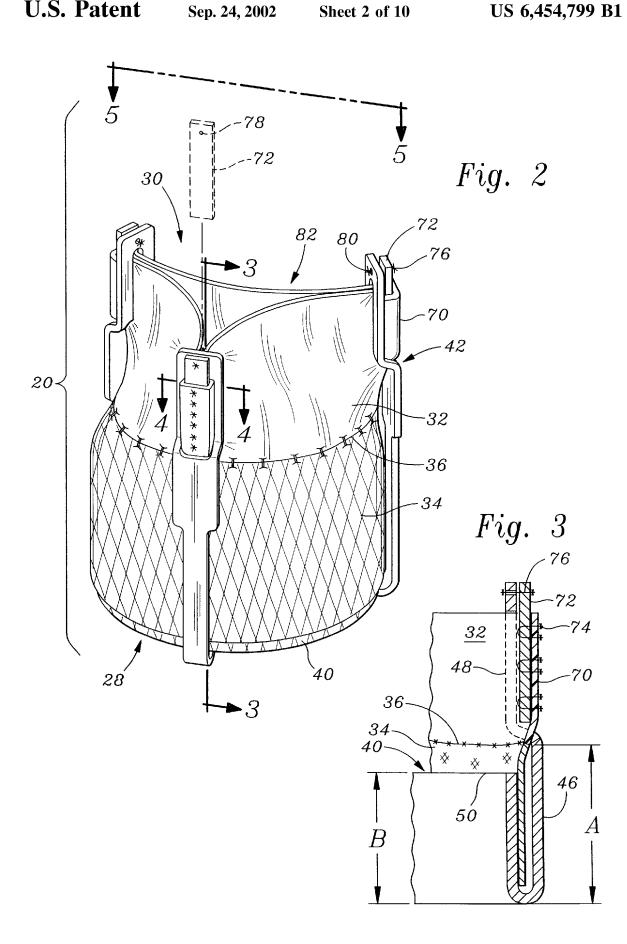
Pavenick, et al.; Development and Initial Experimental Evaluation of a Prosthetic Aortic Valve for Transcatheter Placement, Cardiovascular Radiology, vol. 183, No. 1, pp. 151–154.

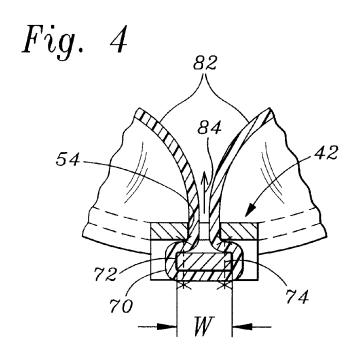
Bailey *Percutaneous Expandable Prosthetic Valves*, VIII—Valvuloplasty, Congenital and Pericardial Heart Disease, pp. 1269–1276.

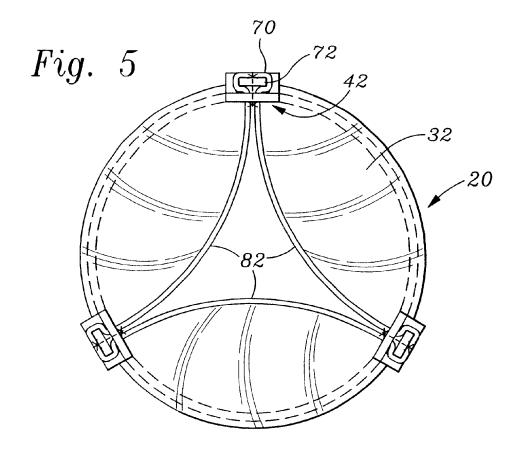


^{*} cited by examiner









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