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(54) **PERCUTANEOUS REPLACEMENT HEART VALVE AND A DELIVERY AND IMPLANTATION SYSTEM**

(58) **Field of Classification Search**
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(56) **References Cited**

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U.S. PATENT DOCUMENTS

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3,014,024 A 12/1961 Lieberman et al.
3,029,819 A 4/1962 Edward

(Continued)

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FOREIGN PATENT DOCUMENTS

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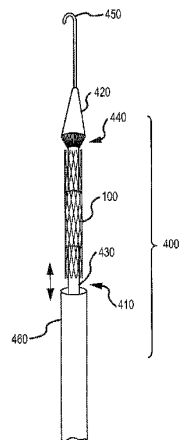
CPC **A61F 2/2412** (2013.01); **A61B 8/12** (2013.01); **A61F 2/24** (2013.01); **A61F 2/2415** (2013.01); **A61F 2/2418** (2013.01); **A61F 2/2427** (2013.01); **A61F 2/2433** (2013.01);

(57) **ABSTRACT**

A method of making a replacement heart valve device whereby a fragment of biocompatible tissue material is treated and soaked in one or more alcohol solutions and a solution of glutaraldehyde. The dried biocompatible tissue material is folded and rehydrated in such a way that forms a two- or three-leaflet/cusp valve without affixing of separate cusps or leaflets or cutting slits into the biocompatible tissue material to form the cusps or leaflets. After the biocompatible tissue material is folded, it is affixed at one or more points on the outer surface to the inner cavity or a stent.

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(56) **References Cited**

U.S. PATENT DOCUMENTS

3,105,492 A	10/1963	Jeckel	5,047,050 A	9/1991	Arpesani
3,320,972 A	5/1967	High et al.	5,052,771 A	10/1991	Williams et al.
3,409,914 A	11/1968	Jones	5,061,277 A	10/1991	Carpentier et al.
3,548,417 A	12/1970	Kischer et al.	5,080,660 A	1/1992	Buelna
3,562,820 A	2/1971	Braun	5,139,515 A	8/1992	Robicsek
3,588,920 A	6/1971	Wesolowski	5,163,955 A	11/1992	Love et al.
3,671,979 A	6/1972	Mouloupoulos	5,171,273 A	12/1992	Silver et al.
3,709,175 A	1/1973	Edwards et al.	5,226,889 A	7/1993	Sheiban
3,878,565 A	4/1975	Sauvage	5,261,878 A	11/1993	Galindo
3,945,052 A	3/1976	Liebig	5,282,847 A	2/1994	Trescony et al.
3,966,401 A	6/1976	Hancock et al.	5,326,370 A	7/1994	Love et al.
3,983,581 A	10/1976	Angell et al.	5,326,371 A	7/1994	Love et al.
3,986,828 A	10/1976	Hoffman, Jr. et al.	5,332,402 A	7/1994	Teitelbaum
4,011,947 A	3/1977	Sawyer	5,336,616 A	8/1994	Livesey et al.
4,035,849 A	7/1977	Angell et al.	5,360,443 A	11/1994	Barone et al.
4,055,861 A	11/1977	Carpentier et al.	5,374,539 A	12/1994	Nimni et al.
4,056,854 A	11/1977	Boretos et al.	5,376,110 A	12/1994	Tu et al.
4,060,081 A	11/1977	Yannas et al.	5,383,927 A	1/1995	De Goicoechea et al.
4,082,507 A	4/1978	Sawyer	5,411,552 A	5/1995	Andersen et al.
4,084,268 A	4/1978	Ionescu et al.	5,413,601 A	5/1995	Keshelava
4,106,129 A	8/1978	Carpentier et al.	5,449,384 A	9/1995	Johnson
4,164,045 A	8/1979	Bokros et al.	5,476,506 A	12/1995	Lunn
4,172,295 A	10/1979	Batten	5,480,424 A	1/1996	Cox
4,218,782 A	8/1980	Rygg	5,484,444 A	1/1996	Braunschweiler et al.
4,222,126 A	9/1980	Boretos et al.	5,489,297 A	2/1996	Duran
4,233,493 A	11/1980	Nath et al.	5,500,015 A	3/1996	Deac
4,265,694 A	5/1981	Boretos et al.	5,509,930 A	4/1996	Love
4,291,420 A	9/1981	Reul	5,522,879 A	6/1996	Scopelianos
4,340,977 A	7/1982	Brownlee et al.	5,522,881 A	6/1996	Lentz
4,350,492 A	9/1982	Wright et al.	5,545,215 A	8/1996	Duran
4,364,127 A	12/1982	Pierce et al.	5,549,664 A	8/1996	Hirata et al.
4,388,735 A	6/1983	Ionescu et al.	5,549,666 A	8/1996	Hata et al.
4,423,525 A	1/1984	Vallana et al.	5,554,184 A	9/1996	Machiraju
4,441,216 A	4/1984	Ionescu et al.	5,571,170 A	11/1996	Palmaz et al.
4,456,589 A	6/1984	Holman et al.	5,571,173 A	11/1996	Parodi
4,473,423 A	9/1984	Kolff	5,571,174 A	11/1996	Love et al.
4,477,930 A	10/1984	Totten et al.	5,578,071 A	11/1996	Parodi
4,490,859 A	1/1985	Black et al.	5,578,072 A	11/1996	Barone et al.
4,517,687 A	5/1985	Liebig et al.	5,582,168 A	12/1996	Samuels et al.
4,545,082 A	10/1985	Hood	5,591,229 A	1/1997	Parodi
4,597,762 A	7/1986	Walter et al.	5,634,928 A	6/1997	Fischell et al.
4,600,533 A	7/1986	Chu	5,645,559 A	7/1997	Hachtman et al.
4,631,052 A	12/1986	Kensley	5,653,749 A	8/1997	Love et al.
4,657,133 A	4/1987	Komatsu et al.	5,683,451 A	11/1997	Lenker et al.
4,666,442 A	5/1987	Arru et al.	5,713,953 A	2/1998	Vallana et al.
4,728,328 A	3/1988	Hughes et al.	5,728,152 A	3/1998	Mirsch, II et al.
4,743,231 A	5/1988	Kay et al.	5,733,299 A	3/1998	Sheiban et al.
4,759,758 A	7/1988	Gabbay	5,741,333 A	4/1998	Frid
4,759,759 A	7/1988	Walker et al.	5,746,775 A	5/1998	Levy et al.
4,798,611 A	1/1989	Freeman, Jr.	5,769,780 A	6/1998	Hata et al.
4,801,299 A	1/1989	Brendel et al.	5,782,914 A	7/1998	Schankereli
4,870,966 A	10/1989	Dellon et al.	5,787,887 A	8/1998	Klingenbeck-Regn
4,883,458 A	11/1989	Shiber	5,840,081 A	11/1998	Andersen et al.
4,892,539 A	1/1990	Koch	5,855,601 A	1/1999	Bessler et al.
4,966,604 A	10/1990	Reiss	5,861,028 A	1/1999	Angell
4,976,733 A	12/1990	Giradot	5,862,806 A	1/1999	Cheung
4,979,939 A	12/1990	Shiber	5,876,448 A	3/1999	Thompson et al.
5,006,104 A	4/1991	Smith et al.	5,895,420 A	4/1999	Mirsch, II et al.
5,007,896 A	4/1991	Shiber	5,931,969 A	8/1999	Carpentier et al.
5,011,488 A	4/1991	Ginsburg	5,957,949 A	9/1999	Leonhardt et al.
5,026,366 A	6/1991	Leckrone	5,961,539 A	10/1999	Northup et al.
5,032,128 A	7/1991	Alonso	5,961,549 A	10/1999	Nguyen et al.
5,047,041 A	9/1991	Samuels	5,972,030 A	10/1999	Garrison et al.
			5,976,179 A	11/1999	Inoue
			6,004,328 A	12/1999	Solar
			6,004,330 A	12/1999	Middleman et al.
			6,010,531 A	1/2000	Donlon et al.
			6,029,671 A	2/2000	Stevens et al.
			6,045,576 A	4/2000	Starr et al.
			6,053,938 A	4/2000	Goldmann et al.
			6,091,984 A	7/2000	Perelman et al.
			6,102,944 A	8/2000	Huynh et al.
			6,117,169 A	9/2000	Moe
			6,124,523 A	9/2000	Banas et al.
			6,125,852 A	10/2000	Stevens et al.
			6,126,686 A	10/2000	Badylak et al.
			6,129,756 A	10/2000	Kugler
			6,162,245 A	12/2000	Jayaraman
			6,168,614 B1	1/2001	Andersen et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

6,168,619	B1	1/2001	Dinh et al.	6,736,823	B2	5/2004	Darios et al.
6,171,335	B1	1/2001	Wheatley et al.	6,764,510	B2	7/2004	Vidlund et al.
6,174,327	B1	1/2001	Mertens et al.	6,773,456	B1	8/2004	Gordon et al.
6,186,999	B1	2/2001	Chen	6,773,457	B2	8/2004	Ivancev
6,197,143	B1	3/2001	Bodnar	6,790,229	B1	9/2004	Berrekouw
6,214,055	B1	4/2001	Simionescu et al.	6,792,979	B2	9/2004	Konya et al.
6,221,091	B1	4/2001	Khosravi	6,802,319	B2	10/2004	Stevens et al.
6,231,602	B1	5/2001	Carpentier et al.	6,802,806	B2	10/2004	McCarthy et al.
6,245,102	B1	6/2001	Jayaraman	6,821,297	B2	11/2004	Snyders
6,254,629	B1	7/2001	Inoue	6,821,530	B2	11/2004	Koob et al.
6,254,630	B1	7/2001	Inoue	6,830,584	B1	12/2004	Seguin
6,254,636	B1	7/2001	Peredo	6,893,460	B2	5/2005	Spenser et al.
6,264,691	B1	7/2001	Gabbay	6,896,690	B1	5/2005	Lambrecht et al.
6,269,819	B1	8/2001	Oz et al.	6,908,481	B2*	6/2005	Cribier 623/2.11
6,270,526	B1	8/2001	Cox	6,913,608	B2	7/2005	Liddicoat et al.
6,277,397	B1	8/2001	Shimizu	6,916,338	B2	7/2005	Speziali
6,277,555	B1	8/2001	Duran et al.	6,942,694	B2	9/2005	Liddicoat et al.
6,287,335	B1	9/2001	Drasler et al.	6,951,571	B1	10/2005	Srivastava
6,293,970	B1	9/2001	Wolfenbarger, Jr. et al.	6,961,123	B1	11/2005	Wang et al.
6,312,462	B1	11/2001	McDermott et al.	6,977,231	B1	12/2005	Matsuda
6,312,474	B1	11/2001	Francis et al.	6,986,735	B2	1/2006	Abraham et al.
6,334,873	B1	1/2002	Lane et al.	7,004,925	B2	2/2006	Navia et al.
6,342,069	B1	1/2002	Deac et al.	7,008,763	B2	3/2006	Cheung
6,350,278	B1	2/2002	Lenker et al.	7,011,688	B2	3/2006	Gryska et al.
6,350,282	B1	2/2002	Eberhardt	7,018,404	B2	3/2006	Holmberg et al.
6,352,554	B2	3/2002	De Paulis	7,018,406	B2	3/2006	Seguin et al.
6,352,708	B1	3/2002	Duran et al.	7,022,348	B2	4/2006	Ketharanathan
6,358,275	B1	3/2002	McIlroy et al.	7,025,780	B2	4/2006	Gabbay
6,358,284	B1	3/2002	Fearnot et al.	7,037,333	B2	5/2006	Myers et al.
6,371,980	B1	4/2002	Rudakov et al.	7,039,446	B2	5/2006	Ruchti et al.
6,376,244	B1	4/2002	Atala et al.	7,041,132	B2	5/2006	Quijano et al.
6,378,221	B1	4/2002	Ekholm, Jr. et al.	7,053,051	B2	5/2006	Hendriks et al.
6,383,171	B1	5/2002	Gifford et al.	7,060,092	B2	6/2006	Kuribayashi et al.
6,391,333	B1	5/2002	Li et al.	7,070,616	B2	7/2006	Majercak et al.
6,409,755	B1	6/2002	Vrba	7,077,862	B2	7/2006	Vidlund et al.
6,418,339	B1	7/2002	Essenpreis et al.	7,084,082	B1	8/2006	Shimizu
6,425,916	B1*	7/2002	Garrison et al. 623/2.11	7,138,226	B2	11/2006	Vincek et al.
6,432,712	B1	8/2002	Wolfenbarger, Jr. et al.	7,153,324	B2	12/2006	Case et al.
6,440,167	B2	8/2002	Shimizu	7,160,322	B2	1/2007	Gabbay
6,458,153	B1	10/2002	Bailey et al.	7,164,145	B2	1/2007	Shakespeare
6,461,382	B1	10/2002	Cao	7,166,570	B2	1/2007	Hunter et al.
6,468,313	B1	10/2002	Claeson et al.	7,189,259	B2	3/2007	Simionescu et al.
6,471,723	B1	10/2002	Ashworth et al.	7,213,601	B2	5/2007	Stevens et al.
6,482,227	B1	11/2002	Solvay	7,214,242	B2	5/2007	Abraham et al.
6,482,228	B1	11/2002	Norred	7,232,461	B2	6/2007	Ramer
6,482,240	B1	11/2002	Echmayer et al.	7,261,732	B2	8/2007	Justino
6,491,719	B1	12/2002	Fogarty et al.	7,289,211	B1	10/2007	Walsh, Jr. et al.
6,494,909	B2	12/2002	Greenhalgh	7,309,461	B2	12/2007	Kujawski et al.
6,503,272	B2	1/2003	Duerig et al.	7,311,730	B2	12/2007	Gabbay
6,530,952	B2	3/2003	Vesely	7,318,998	B2	1/2008	Goldstein et al.
6,534,004	B2	3/2003	Chen et al.	7,329,279	B2	2/2008	Haug et al.
6,540,782	B1	4/2003	Snyders	7,331,993	B2	2/2008	White
6,553,681	B2	4/2003	Ekholm, Jr. et al.	7,354,702	B2	4/2008	Dai et al.
6,558,418	B2	5/2003	Carpentier et al.	RE40,404	E	6/2008	Schmitt et al.
6,565,960	B2	5/2003	Koob et al.	7,381,218	B2	6/2008	Schreck
6,569,200	B2	5/2003	Wolfenbarger, Jr. et al.	7,381,219	B2	6/2008	Salahieh et al.
6,582,458	B1	6/2003	White et al.	7,399,315	B2	7/2008	Iobbi
6,582,462	B1	6/2003	Andersen et al.	7,427,291	B2	9/2008	Liddicoat et al.
6,582,464	B2	6/2003	Gabbay	7,431,725	B2	10/2008	Stack et al.
6,599,524	B2	7/2003	Li et al.	7,468,073	B2	12/2008	Johnson et al.
6,610,088	B1	8/2003	Gabbay	7,473,237	B2	1/2009	Navia et al.
6,624,890	B2	9/2003	Backman et al.	7,481,838	B2	1/2009	Carpentier et al.
6,626,938	B1	9/2003	Butaric et al.	7,503,929	B2	3/2009	Johnson et al.
6,652,577	B2	11/2003	Gianotti	7,510,571	B2	3/2009	Spiridigliozzi et al.
6,652,578	B2*	11/2003	Bailey et al. 623/1.24	7,510,575	B2	3/2009	Spenser et al.
6,666,886	B1	12/2003	Tranquillo et al.	7,524,330	B2	4/2009	Berrekouw
6,676,698	B2	1/2004	McGuckin, Jr.	7,556,646	B2*	7/2009	Yang et al. 623/2.11
6,682,537	B2	1/2004	Ouriel et al.	7,566,343	B2	7/2009	Jenson et al.
6,682,559	B2	1/2004	Myers et al.	7,585,321	B2	9/2009	Cribier
6,685,739	B2	2/2004	Dimatteo et al.	7,604,661	B2	10/2009	Pavcnik et al.
6,696,074	B2	2/2004	Dia et al.	7,618,446	B2	11/2009	Andersen et al.
6,702,826	B2	3/2004	Liddicoat et al.	7,622,276	B2	11/2009	Cunanan et al.
6,719,788	B2	4/2004	Cox	7,628,805	B2	12/2009	Spenser et al.
6,719,789	B2	4/2004	Cox	7,648,676	B2	1/2010	Mills et al.
6,733,525	B2	5/2004	Yang et al.	7,670,368	B2	3/2010	Hill et al.
				7,708,775	B2	5/2010	Rowe et al.
				7,758,632	B2	7/2010	Hojeibane et al.
				7,780,722	B2	8/2010	Thielen et al.
				7,789,909	B2	9/2010	Andersen et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

7,846,203 B2	12/2010	Cribier	2005/0228494 A1	10/2005	Marquez
7,846,204 B2	12/2010	Letac et al.	2005/0241981 A1	11/2005	Gupta et al.
7,871,431 B2	1/2011	Gurm et al.	2005/0246035 A1	11/2005	Wolfenbarger et al.
7,892,281 B2	2/2011	Seguin et al.	2005/0247320 A1	11/2005	Stack et al.
7,914,576 B2	3/2011	Navia et al.	2005/0267529 A1	12/2005	Crockett et al.
RE42,395 E	5/2011	Wright et al.	2006/0004439 A1	1/2006	Spenser et al.
7,967,833 B2	6/2011	Sterman et al.	2006/0004443 A1	1/2006	Liddicoat et al.
7,981,151 B2	7/2011	Rowe	2006/0020336 A1	1/2006	Liddicoat
8,002,825 B2	8/2011	Letac et al.	2006/0025800 A1	2/2006	Suresh
8,007,992 B2	8/2011	Tian et al.	2006/0041306 A1	2/2006	Vidlund
8,057,540 B2	11/2011	Letac et al.	2006/0074486 A1	4/2006	Liddicoat et al.
8,080,054 B2	12/2011	Rowe	2006/0089708 A1	4/2006	Osse et al.
8,105,375 B2	1/2012	Navia et al.	2006/0111733 A1	5/2006	Shriver
8,512,401 B2	8/2013	Murray et al.	2006/0129225 A1	6/2006	Kopia et al.
8,512,403 B2	8/2013	Navia et al.	2006/0134079 A1	6/2006	Sih et al.
2001/0010017 A1	7/2001	Cribier et al.	2006/0140916 A1	6/2006	Siani-Rose et al.
2001/0023372 A1	9/2001	Chen et al.	2006/0173475 A1	8/2006	Lafontaine et al.
2001/0049558 A1	12/2001	Liddicoat et al.	2006/0178740 A1	8/2006	Stacchino et al.
2002/0005073 A1	1/2002	Tompkins et al.	2006/0190074 A1	8/2006	Hill et al.
2002/0028243 A1	3/2002	Masters	2006/0193885 A1	8/2006	Neethling et al.
2002/0029783 A1	3/2002	Stevens et al.	2006/0195010 A1	8/2006	Arnal et al.
2002/0032481 A1 *	3/2002	Gabbay 623/2.11	2006/0195183 A1	8/2006	Navia et al.
2002/0037940 A1	3/2002	Koob et al.	2006/0206203 A1	9/2006	Yang et al.
2002/0042621 A1	4/2002	Liddicoat et al.	2006/0229701 A1	10/2006	Gurm et al.
2002/0052651 A1	5/2002	Myers et al.	2006/0240063 A9	10/2006	Hunter et al.
2002/0091441 A1	7/2002	Guzik	2006/0240064 A9	10/2006	Hunter et al.
2002/0095167 A1	7/2002	Liddicoat et al.	2006/0259134 A1	11/2006	Schwammenthal et al.
2002/0095994 A1	7/2002	Vesley et al.	2006/0259135 A1	11/2006	Navia et al.
2002/0123789 A1	9/2002	Francis et al.	2006/0259137 A1	11/2006	Artof et al.
2002/0128708 A1	9/2002	Northrup et al.	2006/0265056 A1	11/2006	Nguyen et al.
2002/0151970 A1	10/2002	Garrison et al.	2006/0287571 A1	12/2006	Gozzi et al.
2003/0027332 A1	2/2003	Lafrance et al.	2006/0292125 A1	12/2006	Kellar et al.
2003/0078659 A1	4/2003	Yang	2007/0010857 A1	1/2007	Sugimoto et al.
2003/0102000 A1	6/2003	Stevens et al.	2007/0043431 A1	2/2007	Melsheimer
2003/0130727 A1	7/2003	Drasler et al.	2007/0050014 A1	3/2007	Johnson
2003/0130729 A1	7/2003	Paniagua et al.	2007/0050022 A1	3/2007	Vidlund et al.
2003/0130731 A1	7/2003	Vidlund et al.	2007/0056346 A1	3/2007	Spenser et al.
2003/0149477 A1	8/2003	Gabbay	2007/0060932 A1	3/2007	Stack et al.
2003/0153974 A1	8/2003	Spenser et al.	2007/0061008 A1	3/2007	Salahieh et al.
2003/0187362 A1	10/2003	Murphy et al.	2007/0100426 A1	5/2007	Rudakov et al.
2003/0195620 A1	10/2003	Huynh et al.	2007/0104395 A1	5/2007	Kinigakis et al.
2003/0204023 A1	10/2003	Koob et al.	2007/0128174 A1	6/2007	Kleinsek et al.
2003/0209835 A1	11/2003	Chun et al.	2007/0173861 A1	7/2007	Strommer et al.
2003/0212460 A1	11/2003	Darios et al.	2007/0203575 A1	8/2007	Forster et al.
2003/0212462 A1	11/2003	Gryska et al.	2007/0213813 A1	9/2007	Von Segesser et al.
2003/0217415 A1	11/2003	Crouch et al.	2007/0250154 A1	10/2007	Greenberg et al.
2004/0024452 A1	2/2004	Kruse et al.	2007/0263226 A1	11/2007	Kurtz et al.
2004/0039442 A1	2/2004	St. Goar	2007/0276432 A1	11/2007	Stack et al.
2004/0055608 A1	3/2004	Stevens et al.	2007/0276461 A1	11/2007	Andreas et al.
2004/0059418 A1	3/2004	McKay et al.	2008/0004686 A1	1/2008	Hunt et al.
2004/0098092 A1	5/2004	Butaric et al.	2008/0009667 A1	1/2008	Longhini et al.
2004/0158321 A1	8/2004	Reuter et al.	2008/0009940 A1	1/2008	Cribier
2004/0193261 A1	9/2004	Berrekouw	2008/0029105 A1	2/2008	Stevens et al.
2004/0230285 A1	11/2004	Gifford, III et al.	2008/0039871 A1	2/2008	Wallace et al.
2004/0243153 A1	12/2004	Liddicoat et al.	2008/0039926 A1	2/2008	Majercak et al.
2004/0243229 A1	12/2004	Vidlund et al.	2008/0058798 A1	3/2008	Wallace et al.
2005/0004668 A1	1/2005	Aklog et al.	2008/0082113 A1	4/2008	Bishop et al.
2005/0027369 A1	2/2005	Eldridge et al.	2008/0102439 A1	5/2008	Tian et al.
2005/0043819 A1	2/2005	Schmidt et al.	2008/0133004 A1	6/2008	White
2005/0096673 A1	5/2005	Stack et al.	2008/0147182 A1	6/2008	Righini et al.
2005/0113910 A1	5/2005	Paniagua et al.	2008/0154356 A1	6/2008	Obermiller et al.
2005/0137681 A1	6/2005	Shoemaker et al.	2008/0177381 A1	7/2008	Navia et al.
2005/0137682 A1	6/2005	Justino	2008/0183280 A1	7/2008	Agnew et al.
2005/0142163 A1	6/2005	Hunter et al.	2008/0183283 A1	7/2008	Downing
2005/0147562 A1	7/2005	Hunter et al.	2008/0190989 A1	8/2008	Crews et al.
2005/0147599 A1	7/2005	Hunter et al.	2008/0195200 A1	8/2008	Vidlund et al.
2005/0147643 A1	7/2005	Hunter et al.	2008/0199843 A1	8/2008	Haverich et al.
2005/0148512 A1	7/2005	Hunter et al.	2008/0200977 A1	8/2008	Paul et al.
2005/0158274 A1	7/2005	Hunter et al.	2009/0005857 A1	1/2009	Ischinger
2005/0159811 A1	7/2005	Lane	2009/0030511 A1	1/2009	Paniagua et al.
2005/0169958 A1	8/2005	Hunter et al.	2009/0043383 A1	2/2009	McGregor et al.
2005/0169959 A1	8/2005	Hunter et al.	2009/0054969 A1	2/2009	Salahieh
2005/0175657 A1	8/2005	Hunter et al.	2009/0062907 A1	3/2009	Quijano et al.
2005/0187618 A1	8/2005	Gabbay	2009/0112309 A1	4/2009	Jaramillo et al.
2005/0191248 A1	9/2005	Hunter et al.	2009/0132032 A9	5/2009	Cribier
			2009/0157175 A1	6/2009	Benichou
			2009/0164005 A1	6/2009	Dove et al.
			2009/0187241 A1	7/2009	Melsheimer
			2009/0248149 A1	10/2009	Gabbay

(56)

References Cited

U.S. PATENT DOCUMENTS

2009/0254175 A1 10/2009 Quijano et al.
 2009/0281609 A1 11/2009 Benichou et al.
 2010/0030259 A1 2/2010 Pavcnik et al.
 2010/0036479 A1 2/2010 Hill et al.
 2010/0036484 A1 2/2010 Hariton et al.
 2010/0043197 A1 2/2010 Abbate et al.
 2010/0048987 A1 2/2010 Khairkahan
 2010/0049312 A1 2/2010 Edoga et al.
 2010/0131054 A1 5/2010 Tuval et al.
 2010/0161036 A1 6/2010 Pintor et al.
 2010/0185277 A1 7/2010 Braido et al.
 2010/0217382 A1 8/2010 Chau et al.
 2010/0234878 A1 9/2010 Hruska
 2010/0241069 A1 9/2010 Hatten
 2010/0249918 A1 9/2010 Zhang
 2010/0256749 A1 10/2010 Tran et al.
 2010/0256751 A1 10/2010 Rowe et al.
 2010/0312333 A1 12/2010 Navia et al.
 2011/0004299 A1 1/2011 Navia et al.
 2011/0015728 A1 1/2011 Jimenez et al.
 2011/0040375 A1 2/2011 Letac et al.
 2011/0087322 A1 4/2011 Letac et al.
 2011/0137409 A1 6/2011 Yang et al.
 2011/0146361 A1 6/2011 Davidson et al.
 2011/0153009 A1 6/2011 Navia et al.
 2011/0166636 A1 7/2011 Rowe
 2011/0178597 A9 7/2011 Navia et al.
 2011/0218619 A1 9/2011 Benichou et al.
 2011/0224607 A1 9/2011 Vogelbaum et al.
 2011/0240511 A1 10/2011 Bolton et al.
 2011/0300625 A1 12/2011 Paniagua et al.
 2011/0301700 A1 12/2011 Fish et al.
 2012/0078343 A1 3/2012 Fish
 2012/0078356 A1 3/2012 Fish et al.
 2012/0095551 A1 4/2012 Navia et al.
 2012/0158128 A1 6/2012 Gautam et al.
 2012/0185038 A1 7/2012 Fish et al.
 2012/0310041 A1 12/2012 Paniagua et al.
 2014/0039613 A1 2/2013 Navia et al.
 2013/0304201 A1 11/2013 Navia et al.

FOREIGN PATENT DOCUMENTS

EP 1441672 9/2011
 EP 2055266 2/2012
 EP 1621162 5/2012
 EP 2260796 2/2013
 JP 9-501594 2/1997
 JP 2001-500761 1/2001
 JP 2005-103321 4/2005
 RU 2355361 C 5/2009
 WO 91/17720 11/1991
 WO 92/17118 10/1992
 WO 98/29057 7/1998
 WO 99/30646 6/1999
 WO 00/12164 3/2000
 WO 01/02031 1/2001
 WO 03/047468 6/2003
 WO 03/092554 11/2003
 WO 2004/026124 4/2004
 WO 2004/082527 9/2004
 WO 2006/095342 9/2006
 WO 2007/138572 12/2007
 WO 2008/063537 8/2008
 WO 2008/106531 9/2008
 WO 2009/052188 4/2009
 WO 2009/149462 12/2009
 WO 2009/156471 12/2009
 WO 2010/024801 3/2010
 WO 2010/027363 3/2010
 WO 2010/080594 7/2010
 WO 2010/117541 10/2010
 WO 2011/109433 3/2011
 WO 2011/109450 9/2011

WO 2012/006124 1/2012
 WO 2012/040643 3/2012
 WO 2012/082952 6/2012

OTHER PUBLICATIONS

Cross-reference is made to U.S. Appl. No. 14/268,184, filed May 2, 2014, and its associated Preliminary Amendment.
 Cross-reference is made to U.S. Appl. No. 14/268,190, filed May 2, 2014, and its associated Preliminary Amendment.
 Cross-reference is made to U.S. Appl. No. 14/284,049, filed May 21, 2014, and its associated Preliminary Amendment.
 Cross-reference is made to U.S. Appl. No. 14/284,063, filed May 21, 2014, and its associated Preliminary Amendment.
 Paniagua, David et al., Abstract 4622: "Percutaneous Implantation of a Low Profile, Dry Membrane, Heart Valve in an Integrated Delivery System in the Aortic and Pulmonary Positions: One-month Animal Results," Circulation, American Heart Association, Inc., 2009; vol. 120: pp. 982.
 Pathak, CP et al., "Treatment of bioprosthetic heart valve tissue with long chain alcohol solution to lower calcification potential" J Biomed Mater Res A. Apr. 1, 2004;69(1), pp. 140-144.
 Pavenik, Susan, M.D., PhD et al., "Development and Initial Experimental Evaluation of a Prosthetic Aortic Valve for Transcatheter Placement" Cardiovascular Radiology, Apr. 1992, pp. 151-154.
 Pick, Adam, "True or False: An Edwards Lifesciences' Tissue Valve Replacement Requires 1,800 Hand-Sewn Stitches" <http://heart-valve-surgery.com/heart-surgery-blog/2008/02/26>. printed Aug. 13, 2010.
 Pohl, M. et al., "In vitro testing of artificial heart valves; comparison between Newtonian and non-Newtonian fluids" Artif Argns, Jan. 1996; 20(1); pp. 37-46.
 Purinya, B. et al., "Biomechanical and Structural Properties of the Implanted Bioprosthetic Valve Leaflets" J. of Biomechanis, vol. 27, Iss 1, Jan. 1994 pp. 1-11 Elsevier Science Ltd, 1993.
 Sacks, MS et al., "Bioprosthetic heart valve heterograft biomaterials: structure, mechanical behavior and computational simulation" Expert Rev Med Devices, Nov. 2006; 3(6): pp. 817-834 (Abstract only).
 Sacks, MS et al., "Collagen fiber architecture of bovine pericardium" ASAIO J, Jul. 1, 1994, 40(3), pp. 632-637.
 Sacks, M S et al., "A small angle light scattering device for planar connective tissue microstructural analysis" Ann Biomed Eng, Jul. 1, 1997, 25(4), pp. 678-689.
 Sacks, Michael S, "Incorporation of experimentally-derived fiber orientation into a structural constitutive model for planar collagenous tissues" J. Biomech Eng, Apr. 1, 2003, 125(2), pp. 280-287.
 Sacks, Michael S. et al., "Quantification of the fiber architecture and biaxial mechanical behavior of porcine intestinal submucosa" J of Biomedical Research, vol. 46, Iss 1, Jul. 1999, pp. 1-10.
 Samouillan, V. et al., "Comparison of chemical treatments on the chain dynamics and thermal stability of bovine pericardium collagen" J Biomed Mater Res A. Feb. 1, 2003;64(2), pp. 330-338.
 Schmidt, Dorte et al., "Tissue engineering of heart valves using decellularized xenogeneic of polymeric starter matrices" Philos Trans R Soc Lond B Bio Sci., Aug. 29, 2007, 362(1484); 1505-1512; published online Jun. 22, 2007, doi: 10.1098/rstb.2007.2131.
 Schoen, Frederick J., "Tissue heart valves: Current challenges and future research perspectives" J of Biomedical Materials Research, vol. 47, Iss 4, Dec. 15, 1999, pp. 439-465.
 Sellaro, Tiffany L., "Effects of Collagen Orientation on the Medium-Term Fatigue Response of Heart Valve Biomaterials" 2003, (published thesis) pp. 40-45.
 Sellaro, Tiffany L. et al., "Effects of Collagen Fiber Orientation on the Response of Biologically Derived Soft Tissue Biomaterials to Cyclic Loading" J. Biomed Mater Res A, Jan. 1, 2007; 80(1): 194-205; published online Oct. 13, 2006 by Wiley InterScience.
 Shandas, Robin PhD et al., "A Method for Determining the Reference Effective Flow Areas for Mechanical Heart Valve Prostheses" Circulation Apr. 25, 2000.
 Shen, Ming et al., "Effect of ethanol and ether in the prevention of calcification of bioprostheses" Ann Thorac Surg. May 2001;71(5 Suppl), pp. 413-416.

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