



Heart Valve Programs  
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January 24, 2012

**VIA EMAIL**

Mr. David Miller  
Chairman, Supervisory Panel  
525 Vine Street  
Suite 2300  
Cincinnati, OH 45202

Dear Dave:

Enclosed is the annual report of outlet strut fracture statistics for Björk-Shiley Convexo-Concave (BSCC) heart valves prepared for the U.S. Food and Drug Administration for the period ending December 31, 2011.

Please do not hesitate to contact me if you have any questions.

Sincerely,

A handwritten signature in cursive script that reads "Denise Schoepflin".

Denise Schoepflin

Enclosure

SEMI-ANNUAL REPORT OF  
BSCC VALVE FRACTURE STATISTICS THROUGH  
DECEMBER 31, 2011

**I. FRACTURES REPORTED TO SHILEY**

THERE WERE NO FRACTURES REPORTED TO SHILEY BETWEEN JANUARY 1, 2011 AND DECEMBER 31, 2011.

**BSCC 60 DEGREE VALVES**  
NONE

**BSCC 70 DEGREE VALVES**  
NONE

**VALVES WITH UNKNOWN SERIAL NUMBERS**  
NONE

**EXCLUDED EVENTS**

AS OF DECEMBER 31, 2011, THERE ARE SEVENTEEN EVENTS (UNKNOWN SERIAL NUMBERS) THAT ARE NOT INCLUDED IN THE ACTUARIAL STATISTICS DUE TO INADEQUATE INFORMATION; I.E., THE AVAILABLE INFORMATION IS INSUFFICIENT TO PLACE THESE VALVES INTO ANY RISK CATEGORIES.

**II. REPORTED FRACTURES, ESTIMATED PERSON YEARS, AND RATES OF REPORTED FRACTURE STRATIFIED BY  
U.S., NON-U.S., AND TOTAL WORLDWIDE DISTRIBUTION OF BSCC 60 DEGREE VALVES AS OF DECEMBER 31, 2011**

Risk Group	Size/ Position	Welder Group	Weld Date	U.S.			NON-U.S.			WORLDWIDE		
				Reported Fractures	Estimated Person Years	Rate of Reported Fracture (%/Year)	Reported Fractures	Estimated Person Years	Rate of Reported Fracture (%/Year)	Reported Fractures	Estimated Person Years	Rate of Reported Fracture (%/Year)
1	33/M	A	Jan. 81 - June 82	6	1812	0.33	4	1035	0.39	10	2847	0.35
2	33/M	A	<1980, Jul. 82-March 84	4	2885	0.14	3	1995	0.15	7	4880	0.14
3	33/M	B	<1980, Jan. 81-March 84	7	1480	0.47	4	1286	0.31	11	2766	0.40
4	33/M	C	<1980, Jan. 81-March 84	17	1606	1.06	6	1472	0.41	23	3078	0.75
5	31/M	A	Jan. 81 - June 82	10	6209	0.16	9	7799	0.12	19	14008	0.14
6	31/M	B	Jan. 81 - June 82	21	7541	0.28	22	10437	0.21	43	17978	0.24
7	31/M	C	Jan. 81 - June 82	20	5273	0.38	30	7846	0.38	50	13119	0.38
8	31/M	A	<1980, July 82 - March 8	3	9083	0.03	14	18331	0.08	17	27414	0.06
9	31/M	B	<1980, July 82 - March 8	10	3093	0.32	4	4411	0.09	14	7504	0.19
10	31/M	C	<1980, July 82 - March 8	3	1226	0.24	5	1393	0.36	8	2619	0.31
11	29/M	A	Jan. 81 - June 82	5	7439	0.07	6	11146	0.05	11	18585	0.06
12	29/M	B	Jan. 81 - June 82	15	10916	0.14	19	18154	0.10	34	29070	0.12
13	29/M	C	Jan. 81 - June 82	19	6351	0.30	29	10921	0.27	48	17272	0.28
14	29-33/A	A	Jan. 81 - June 82	1	2661	0.04	0	3124	0.00	1	5785	0.02
15	29-33/A	B	Jan. 81 - June 82	1	1843	0.05	2	2701	0.07	3	4544	0.07
16	29-33/A	C	Jan. 81 - June 82	6	2728	0.22	3	4120	0.07	9	6848	0.13
17	29/M	A,B,C	<1980, July 82 - March 8	5	15293	0.03	20	30295	0.07	25	45588	0.05
18	29-33/A or M	A,B,C	1980	9	23270	0.04	12	53090	0.02	21	76360	0.03
19	23 or 27/A or M	A,B,C	<=March 84	50	152172	0.03	64	270992	0.02	114	423164	0.03
20	29-33/A	A,B,C	<1980, July 82 - March 8	0	4622	0.00	1	12111	0.01	1	16733	0.01
21	21 or 25/A or M	A,B,C	<=March 84	14	198981	0.01	8	278749	0.00	22	477730	0.00
	21-33/A or M	A,B,C	>=April 84									
	<b>TOTAL</b>			<b>226</b>	<b>466484</b>		<b>265</b>	<b>751408</b>		<b>491</b>	<b>1217892</b>	

**III. VALVES BELIEVED IMPLANTED AND ESTIMATED NUMBER OF VALVES CURRENTLY IMPLANTED STRATIFIED BY U.S., NON-U.S., AND TOTAL WORLDWIDE DISTRIBUTION OF BSCC 60 DEGREE VALVES AS OF DECEMBER 31, 2011**

Risk Group	Size/ Position	Welder Group	Weld Date	Estimated Fracture Rate (%/Year)	TOTAL NUMBER OF VALVES BELIEVED TO HAVE BEEN IMPLANTED			NUMBER OF VALVES ESTIMATED TO BE CURRENTLY IMPLANTED IN LIVING PATIENTS		
					U.S.	Non-U.S.	Worldwide	U.S.	Non-U.S.	Worldwide
1	33/M	A	Jan. 81 - June 82	1.28	140	81	221	28	17	45
2	33/M	A	<1980, July 82-March 84	0.46	223	154	377	44	30	74
3	33/M	B	<1980, Jan. 81-March 84	1.36	116	99	215	24	19	43
4	33/M	C	<1980, Jan. 81-March 84	2.82	133	116	249	33	25	58
5	31/M	A	Jan. 81 - June 82	0.43	469	591	1060	86	109	195
6	31/M	B	Jan. 81 - June 82	0.87	579	803	1382	112	157	269
7	31/M	C	Jan. 81 - June 82	1.39	408	610	1018	81	124	205
8	31/M	A	<1980, July 82 - March 84	0.18	689	1387	2076	128	254	382
9	31/M	B	<1980, July 82 - March 84	0.71	243	340	583	51	67	118
10	31/M	C	<1980, July 82 - March 84	0.88	96	110	206	20	23	43
11	29/M	A	Jan. 81 - June 82	0.19	559	839	1398	100	151	251
12	29/M	B	Jan. 81 - June 82	0.35	827	1381	2208	153	259	412
13	29/M	C	Jan. 81 - June 82	1.05	489	842	1331	96	165	261
14	29-33/A	A	Jan. 81 - June 82	0.17	163	191	354	49	57	106
15	29-33/A	B	Jan. 81 - June 82	0.21	113	166	279	34	50	84
16	29-33/A	C	Jan. 81 - June 82	0.57	171	255	426	54	78	132
17	29/M	A,B,C	<1980, July 82 - March 84	0.13	1161	2305	3466	216	432	648
18	29-33/A or M	A,B,C	1980	0.11	1670	3813	5483	304	712	1016
19	23 or 27/A or M	A,B,C	<=March 84	0.09	9880	17716	27596	2560	4560	7120
20	29-33/A	A,B,C	<1980, July 82 - March 84	0.03	286	742	1028	88	223	311
21	21 or 25/A or M	A,B,C	<=March 84	0.01	12815	17938	30753	3588	5029	8617
	21-33/A or M	A,B,C	>=April 84							
TOTAL					31230	50479	81709	7849	12541	20390

IV. REPORTED FRACTURES AND RATES OF REPORTED FRACTURE FOR THE CURRENT (DECEMBER 31, 2011) AND PREVIOUS THREE REPORTS FOR THE TOTAL WORLDWIDE DISTRIBUTION OF BSCC 60 DEGREE VALVES

Risk Size/ Group Position	Welder Group	Weld Date	DECEMBER 31, 2008		DECEMBER 31, 2009		DECEMBER 31, 2010		DECEMBER 31, 2011	
			Reported Fractures	Rate of Fracture (%/Year)	Reported Fractures	Rate of Fracture (%/Year)	Reported Fractures	Rate of Fracture (%/Year)	Reported Fractures	Rate of Fracture (%/Year)
1 33/M	A	Jan. 81 - June 82	10	0.37	10	0.36	10	0.36	10	0.35
2 33/M	A	<1980, July 82-March 84	7	0.15	7	0.15	7	0.15	7	0.14
3 33/M	B	<1980, Jan. 81-March 84	11	0.42	11	0.41	11	0.40	11	0.40
4 33/M	C	<1980, Jan. 81-March 84	23	0.78	23	0.77	23	0.76	23	0.75
5 31/M	A	Jan. 81 - June 82	19	0.14	19	0.14	19	0.14	19	0.14
6 31/M	B	Jan. 81 - June 82	43	0.25	43	0.25	43	0.24	43	0.24
7 31/M	C	Jan. 81 - June 82	50	0.40	50	0.39	50	0.39	50	0.38
8 31/M	A	<1980, July 82 - March 84	17	0.06	17	0.06	17	0.06	17	0.06
9 31/M	B	<1980, July 82 - March 84	14	0.20	14	0.19	14	0.19	14	0.19
10 31/M	C	<1980, July 82 - March 84	8	0.32	8	0.32	8	0.31	8	0.31
11 29/M	A	Jan. 81 - June 82	11	0.06	11	0.06	11	0.06	11	0.06
12 29/M	B	Jan. 81 - June 82	34	0.12	34	0.12	34	0.12	34	0.12
13 29/M	C	Jan. 81 - June 82	48	0.29	48	0.29	48	0.28	48	0.28
14 29-33/A	A	Jan. 81 - June 82	1	0.02	1	0.02	1	0.02	1	0.02
15 29-33/A	B	Jan. 81 - June 82	3	0.07	3	0.07	3	0.07	3	0.07
16 29-33/A	C	Jan. 81 - June 82	9	0.14	9	0.14	9	0.13	9	0.13
17 29/M	A,B,C	<1980, July 82 - March 84	25	0.06	25	0.06	25	0.06	25	0.05
18 29-33/A or M	A,B,C	1980	21	0.03	21	0.03	21	0.03	21	0.03
19 23 or 27/A or M	A,B,C	<=March 84	114	0.03	114	0.03	114	0.03	114	0.03
20 29-33/A	A,B,C	<1980, July 82 - March 84	1	0.01	1	0.01	1	0.01	1	0.01
21 21 or 25/A or M	A,B,C	<=March 84	21	0.00	21	0.00	22	0.00	22	0.00
21 21-33/A or M	A,B,C	>=April 84								
TOTAL			490		490		491		491	

V. REPORTED FRACTURES, ESTIMATED PERSON YEARS, RATES OF REPORTED FRACTURE, VALVES BELIEVED IMPLANTED, AND ESTIMATED NUMBER OF VALVES CURRENTLY IMPLANTED FOR BSCC 70 DEGREE VALVES AS OF DECEMBER 31, 2011

<u>Risk Group</u>	<u>Size/Position</u>	<u>Welder Group</u>	<u>Estimated Fracture Rate (%/Year)</u>	<u>Reported Fractures</u>	<u>Estimated Person Years</u>	<u>Rate of Reported Fracture (%/Year)</u>	<u>Total Valves Believed To Have Been Implanted</u>	<u>Number of Valves Estimated To Be Currently Implanted In Living Patients</u>
95-1	31 - 33 M	D	1.58	35	5331	0.66	427	95
95-2	31 - 33 M	E	3.29	14	1202	1.17	101	26
95-3	29 M or 29-33 A	D	0.64	23	7647	0.30	562	125
95-4	29 M or 29-33 A	E	2.68	24	2478	0.97	195	53
95-5	23 or 27/A or M	D	0.31	17	15717	0.11	1037	274
95-6	23 or 27/A or M	E	1.26	28	7727	0.36	529	147
95-7	17-21 or 25/A or M	D or E	0.21	14	19080	0.07	1196	349
TOTALS				155	59,182		4047	1069

VI. REPORTED FRACTURES AND RATES OF REPORTED FRACTURE FOR THE CURRENT (DECEMBER 31, 2011) AND PREVIOUS THREE REPORTS FOR THE TOTAL WORLDWIDE DISTRIBUTION OF BSCC 70 DEGREE VALVES

Risk Group	Size/Position	Welder Group	DECEMBER 31, 2008		DECEMBER 31, 2009		DECEMBER 31, 2010		DECEMBER 31, 2011	
			Reported Fractures	Rate of Reported Fracture (%/Year)	Reported Fractures	Rate of Reported Fracture (%/Year)	Reported Fractures	Rate of Reported Fracture (%/Year)	Reported Fractures	Rate of Reported Fracture (%/Year)
95-1	31 - 33 M	D	35	0.69	35	0.68	35	0.67	35	0.66
95-2	31 - 33 M	E	14	1.22	14	1.20	14	1.18	14	1.17
95-3	29 M or 29-33 A	D	23	0.32	23	0.31	23	0.31	23	0.30
95-4	29 M or 29-33 A	E	24	1.02	24	1.00	24	0.98	24	0.97
95-5	23 or 27/A or M	D	17	0.11	17	0.11	17	0.11	17	0.11
95-6	23 or 27/A or M	E	28	0.38	28	0.38	28	0.37	28	0.36
95-7	17-21 or 25/A or M	D or E	14	0.08	14	0.08	14	0.07	14	0.07
TOTALS			155		155		155		155	