

SEMI-ANNUAL REPORT OF
BSCC VALVE FRACTURE STATISTICS THROUGH
DECEMBER 31, 2010

I. FRACTURES REPORTED TO SHILEY

ONE FRACTURE WAS REPORTED TO SHILEY BETWEEN JANUARY 1, 2010 AND DECEMBER 31, 2010.

BSCC 60 DEGREE VALVES										
SERIAL NUMBER	FLANGE SIZE	IMPLANT POSITION	WELDDATE	IMPLANT DATE	PATIENT AGE AT DATE OF FRACTURE	DATE OF FRACTURE	DATE REPORTED TO SHILEY	OUTCOME	GEOGRAPHIC LOCATION	EST'D FRACTURE RATE AT DATE OF FRACTURE (%/Year)
25ABC14044	25	Aortic	12/17/1980	5/20/1981	48	12/8/2009	5/17/2010	Death	US	0.020

BSCC 70 DEGREE VALVES

NONE

VALVES WITH UNKNOWN SERIAL NUMBERS

NONE

EXCLUDED EVENTS

AS OF DECEMBER 31, 2010, 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, 2010

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	1786	0.34	4	1021	0.39	10	2807	0.36
2	33/M	A	<1980, Jul. 82-March 84	4	2842	0.14	3	1965	0.15	7	4807	0.15
3	33/M	B	<1980, Jan. 81-March 84	7	1460	0.48	4	1268	0.32	11	2728	0.40
4	33/M	C	<1980, Jan. 81-March 84	17	1584	1.07	6	1451	0.41	23	3035	0.76
5	31/M	A	Jan. 81 - June 82	10	6125	0.16	9	7689	0.12	19	13814	0.14
6	31/M	B	Jan. 81 - June 82	21	7437	0.28	22	10287	0.21	43	17724	0.24
7	31/M	C	Jan. 81 - June 82	20	5202	0.38	30	7737	0.39	50	12939	0.39
8	31/M	A	<1980, July 82 - March 8	3	8950	0.03	14	18072	0.08	17	27022	0.06
9	31/M	B	<1980, July 82 - March 8	10	3046	0.33	4	4343	0.09	14	7389	0.19
10	31/M	C	<1980, July 82 - March 8	3	1207	0.25	5	1372	0.36	8	2579	0.31
11	29/M	A	Jan. 81 - June 82	5	7337	0.07	6	10990	0.05	11	18327	0.06
12	29/M	B	Jan. 81 - June 82	15	10764	0.14	19	17893	0.11	34	28657	0.12
13	29/M	C	Jan. 81 - June 82	19	6265	0.30	29	10768	0.27	48	17033	0.28
14	29-33/A	A	Jan. 81 - June 82	1	2610	0.04	0	3064	0.00	1	5674	0.02
15	29-33/A	B	Jan. 81 - June 82	1	1809	0.06	2	2650	0.08	3	4459	0.07
16	29-33/A	C	Jan. 81 - June 82	6	2677	0.22	3	4041	0.07	9	6718	0.13
17	29/M	A,B,C	<1980, July 82 - March 8	5	15068	0.03	20	29852	0.07	25	44920	0.06
18	29-33/A or M	A,B,C	1980	9	22956	0.04	12	52349	0.02	21	75305	0.03
19	23 or 27/A or M	A,B,C	<=March 84	50	149537	0.03	64	266280	0.02	114	415817	0.03
20	29-33/A	A,B,C	<1980, July 82 - March 8	0	4530	0.00	1	11880	0.01	1	16410	0.01
21	21 or 25/A or M	A,B,C	<=March 84	14	195252	0.01	8	273517	0.00	22	468769	0.00
	21-33/A or M	A,B,C	>=April 84									
	TOTAL			226	458444		265	738489		491	1196933	

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, 2010

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	29	18	47
2	33/M	A	<1980, July 82-March 84	0.46	223	154	377	47	32	79
3	33/M	B	<1980, Jan. 81-March 84	1.36	116	99	215	25	20	45
4	33/M	C	<1980, Jan. 81-March 84	2.82	133	116	249	34	26	60
5	31/M	A	Jan. 81 - June 82	0.43	469	591	1060	90	115	205
6	31/M	B	Jan. 81 - June 82	0.87	579	803	1382	118	165	283
7	31/M	C	Jan. 81 - June 82	1.39	408	610	1018	85	129	214
8	31/M	A	<1980, July 82 - March 84	0.18	689	1387	2076	135	268	403
9	31/M	B	<1980, July 82 - March 84	0.71	243	340	583	53	70	123
10	31/M	C	<1980, July 82 - March 84	0.88	96	110	206	21	25	46
11	29/M	A	Jan. 81 - June 82	0.19	559	839	1398	105	160	265
12	29/M	B	Jan. 81 - June 82	0.35	827	1381	2208	161	273	434
13	29/M	C	Jan. 81 - June 82	1.05	489	842	1331	100	173	273
14	29-33/A	A	Jan. 81 - June 82	0.17	163	191	354	51	59	110
15	29-33/A	B	Jan. 81 - June 82	0.21	113	166	279	35	52	87
16	29-33/A	C	Jan. 81 - June 82	0.57	171	255	426	56	81	137
17	29/M	A,B,C	<1980, July 82 - March 84	0.13	1161	2305	3466	228	455	683
18	29-33/A or M	A,B,C	1980	0.11	1670	3813	5483	319	748	1067
19	23 or 27/A or M	A,B,C	<=March 84	0.09	9880	17716	27596	2668	4756	7424
20	29-33/A	A,B,C	<1980, July 82 - March 84	0.03	286	742	1028	91	232	323
21	21 or 25/A or M	A,B,C	<=March 84	0.01	12815	17938	30753	3737	5238	8975
	21-33/A or M	A,B,C	>=April 84							
TOTAL					31230	50479	81709	8188	13095	21283

IV. REPORTED FRACTURES AND RATES OF REPORTED FRACTURE FOR THE CURRENT (DECEMBER 31, 2010) AND PREVIOUS THREE REPORTS FOR THE TOTAL WORLDWIDE DISTRIBUTION OF BSCC 60 DEGREE VALVES

Risk Group	Size/ Position	Welder Group	Weld Date	JUNE 30, 2008		DECEMBER 31, 2008		DECEMBER 31, 2009		DECEMBER 31, 2010	
				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)
1	33/M	A	Jan. 81 - June 82	10	0.37	10	0.37	10	0.36	10	0.36
2	33/M	A	<1980, July 82-March 84	7	0.15	7	0.15	7	0.15	7	0.15
3	33/M	B	<1980, Jan. 81-March 84	11	0.42	11	0.42	11	0.41	11	0.40
4	33/M	C	<1980, Jan. 81-March 84	23	0.79	23	0.78	23	0.77	23	0.76
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	0.25	43	0.24
7	31/M	C	Jan. 81 - June 82	50	0.40	50	0.40	50	0.39	50	0.39
8	31/M	A	<1980, July 82 - March 84	17	0.07	17	0.06	17	0.06	17	0.06
9	31/M	B	<1980, July 82 - March 84	14	0.20	14	0.20	14	0.19	14	0.19
10	31/M	C	<1980, July 82 - March 84	8	0.32	8	0.32	8	0.32	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	0.29	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	0.14	9	0.13
17	29/M	A,B,C	<1980, July 82 - March 84	25	0.06	25	0.06	25	0.06	25	0.06
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	21	0.00	22	0.00
21	21-33/A or M	A,B,C	>=April 84								
TOTAL				490		490		490		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, 2010

<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	5257	0.67	427	99
95-2	31 - 33 M	E	3.29	14	1185	1.18	101	27
95-3	29 M or 29-33 A	D	0.64	23	7530	0.31	562	131
95-4	29 M or 29-33 A	E	2.68	24	2440	0.98	195	55
95-5	23 or 27/A or M	D	0.31	17	15444	0.11	1037	285
95-6	23 or 27/A or M	E	1.26	28	7595	0.37	529	153
95-7	17-21 or 25/A or M	D or E	0.21	14	18727	0.07	1196	363
<u>TOTALS</u>				<u>155</u>	<u>58,178</u>		<u>4047</u>	<u>1113</u>

VI. REPORTED FRACTURES AND RATES OF REPORTED FRACTURE FOR THE CURRENT (DECEMBER 31, 2010) AND PREVIOUS THREE REPORTS FOR THE TOTAL WORLDWIDE DISTRIBUTION OF BSCC 70 DEGREE VALVES

Risk Group	Size/Position	Welder Group	JUNE 30, 2008		DECEMBER 31, 2008		DECEMBER 31, 2009		DECEMBER 31, 2010	
			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	0.69	35	0.68	35	0.67
95-2	31 - 33 M	E	14	1.23	14	1.22	14	1.20	14	1.18
95-3	29 M or 29-33 A	D	23	0.32	23	0.32	23	0.31	23	0.31
95-4	29 M or 29-33 A	E	24	1.03	24	1.02	24	1.00	24	0.98
95-5	23 or 27/A or M	D	17	0.12	17	0.11	17	0.11	17	0.11
95-6	23 or 27/A or M	E	28	0.39	28	0.38	28	0.38	28	0.37
95-7	17-21 or 25/A or M	D or E	14	0.08	14	0.08	14	0.08	14	0.07
TOTALS			155		155		155		155	