

STATE OF MINNESOTA
COUNTY OF RAMSEY

DISTRICT COURT
SECOND JUDICIAL DISTRICT

Case Type: Personal Injury
(Product Liability)

Shane O’Neill and
Gabriele Sanio-O’Neill h/w

Plaintiff(s)

v.

St. Jude Medical, Inc.
Defendant.

Court File No.

**COMPLAINT AND DEMAND FOR
JURY TRIAL**

Plaintiffs, through counsel, and for their Individual and Class Action Complaint against the Defendant, state as follows:

I. PARTIES

1. Plaintiff Shane O’Neill (“Plaintiff”) brings this suit in his own right and as a Class representative on behalf of a class as set forth below. He is and was at all times material a citizen of the Republic of Ireland, Europe and Canada. He currently resides at 534 Princess Avenue, London, Ontario, Canada, N6B 2B8. At all times material herein he was and is married to Gabriele Sanio-O’Neill (“Spouse Plaintiff”).

2. Spouse Plaintiff Gabriele Sanio-O’Neill brings this suit in her own right as set forth below for injuries and damages she sustained derivative to the harm, losses and injuries sustained by her husband. She is and was at all times material herein a citizen of Germany and Europe. She currently resides at 534 Princess Avenue, London, Ontario, Canada, N6B 2B8.

3. Defendant St. Jude Medical, Inc. (“St. Jude” or “Defendant”) at all times material herein, was a Minnesota corporation with its principal place of business at One Lillehei Plaza, City

of St. Paul, County of Ramsey, State of Minnesota.

4. At all times relevant herein, St. Jude acted by and through its actual, apparent and/or ostensible, agents, servants, officers, employees and physicians, including its wholly owned subsidiaries or divisions such as: St. Jude Medical Europe, Inc., St. Jude Medical UK Ltd., St. Jude Medical France SA, St. Jude Medical GmbH, St. Jude Medical Medizintechnik GmbH, St. Jude Medical Danmark A/S, St. Jude Medical Finland OY, St. Jude Medical Export GmbH (EE/ME/A), St. Jude Medical Italia S.p.A., St. Jude Medical Nederland B.V., St. Jude Medical Portugal, St. Jude Medical Espana S.A., St. Jude Medical Sweden AB, and/or St. Jude Medical AG. According to St. Jude's worldwide website, all of these entities are part, and under the direction and control, of St. Jude Medical International, which division, subsidiary, or entity is headquartered in St. Paul, Ramsey County, Minnesota.

II. FACTS COMMON TO CLASS CERTIFICATION AND ALL SUBSTANTIVE COUNTS

5. Defendant SJM, at all times relevant hereto, is and was engaged in the business of designing, formulating, producing, licensing, manufacturing and/or marketing of heart valve prosthetic replacement and repair products. Among the countries in which SJM markets such products are the member states of the European Economic Union (a/k/a the "European Economic Community") (hereinafter referred to as the "EU").

6. The EU consists of the following sixteen (16) nations: Austria, Belgium, Denmark, Finland, France, Germany, Greece, the Republic of Ireland, Italy, Luxembourg, Portugal, Spain, Sweden, the Netherlands, Norway and the United Kingdom (collectively referred to as "EU members").

7. According to law and treaties governing EU members, once a product receives a "CE" mark from a member state's governing body (which mark signifies that the product in question

meets the requirements of an applicable European Directive), that product may then be marketed throughout the member states of the EU.

8. All EU members have adopted a uniform law that provides remedies to consumers in the EU who have been injured by defective products known as the “Council Directive 85/374/EEC Directive on Product Liability.” (hereinafter “EU Products Directive”).

9. Between 1995 (approximately) through January 21, 2000, Defendant SJM created, designed, tested, obtained market clearance, manufactured, labeled, packaged, distributed, supplied, marketed, sold, advertised, promoted and/or distributed in international commerce, including the EU member states, several combination drug medical devices known as the St. Jude mechanical prosthetic heart valve with Silzone®, the SJM Tailor Annuloplasty Ring, the SJM Epic Valve Stented Tissue Valve, the Séguin Ring with Silzone and the SJM Regent® Valve (hereinafter collectively referred to as “Silzone products”).

10. All Silzone products had in common a proprietary silver coating known as “Silzone” applied to their sewing cuffs.

11. The Silzone coating present on all Silzone products is and was a dangerous and defective product. The Silzone coating is associated with numerous implanted patients suffering malfunctions of their implanted devices, cerebrovascular accidents (*e.g.*, strokes, myocardial infarctions), malignant tumor growth, device explant surgery and/or death.

12. On or about January 21, 2000, SJM discontinued manufacture and distribution of Silzone products and recalled them from the worldwide market.

13. Every patient who has been implanted with a Silzone product that remains implanted in him or her has sustained, at a minimum, subclinical, subacute, cellular and/or subcellular damage from the toxic effects of silver on his or her heart’s tissue. Such injury and damage puts all who

remain implanted with a Silzone product at increased risk of developing therefrom a serious, and potentially fatal, injury or disease as time progresses.

14. On or about January 28, 1997, SJM began to introduce its Silzone product line into EU medical institutions, starting with introduction of its then flagship product, the Master Series mechanical valve prosthesis to whose existing sewing cuff fabric it added a Silzone® coating. At that time thirty-eight (38) Silzone valves were implanted into patients over a few months in the Netherlands and Germany in its LIMRA (Limited International Market Release Authorization) study, a limited and short duration (*i.e.*, 60 days of monitoring) clinical trial that SJM conducted on European subjects to test the safety of the Silzone coating in humans.

15. The valves implanted during this LIMRA study were the sole clinical data set upon which SJM obtained its CE mark from TUV in Germany (which served at all times material herein as the EU's "governing body" on SJM's Silzone products).

16. After obtaining its CE mark on or about July 1, 1997, St Jude began widely selling the Master Series heart valve with Silzone coating throughout the EU at a substantial premium price over its conventionally cuffed product. The Master Series Valve was the predominant Silzone product that was sold.

17. Subsequently, St. Jude began to introduce the remaining Silzone products into the EU member nations shortly after obtaining their requisite CE mark approvals as follows: the SJM Tailor Annuloplasty Ring obtained its CE mark in May 1998; the SJM Epic Valve Stented Tissue Valve obtained its CE mark in September 1998; the Séguin Annuloplasty Ring with Silzone obtained its CE mark in February 1999; and the SJM Regent Valve obtained its CE mark in February 1999.

18. Following the introduction of the Silzone Master Series valve with Silzone in Europe, SJM then obtained regulatory clearance to market this valve product in Canada (1997) and the

United States (1998) .

19. Defendant widely and successfully advertised and promoted the St. Jude mechanical heart valve with Silzone in Europe, as well as in the United States and Canada, in order to create a market for its premium priced, patent-protected Silzone products. This marketing included an orchestrated campaign of scripted promotional efforts that extolled the virtues of the St. Jude mechanical heart valve with Silzone in mitigating the risk of infection, notwithstanding that the Silzone coating, as SJM knew, was not proven to be either safe or efficacious.

20. Defendant did not attempt to demonstrate the clinical efficacy of Silzone products for their sole intended use—preventing or reducing the incidence of prosthetic valve endocarditis—until the Artificial Valve Endocarditis Reduction Trial (“AVERT”), an international, multi-center study commissioned by St. Jude, was undertaken. This study was commenced after SJM had already begun to generally market Silzone products worldwide.

21. In furtherance of its promotional activities to create and maintain a market for its Silzone products, Defendant issued or published representations to physicians and the public, including, *inter alia*, press releases dated September 25, 1997, and March 26, 1998, and commissioned and/or participated in the writing of published medical articles, the thrust of which was that (1) the valve was silver-coated; (2) silver had long had known antimicrobial properties; (3) the silver coating was permanent and/or non- or minimally leaching; (4) the silver coating on the sewing cuff was an advancement in prosthetic implant technology that would be safer for patients; (5) the silver coating was efficacious in promoting better healing following implantation surgery; and/or (6) the silver coating was efficacious in preventing or mitigating the incidence of prosthetic valve endocarditis. St. Jude made or instigated the making of these representations notwithstanding that Silzone-coated products were not proven to be safe and effective in appropriately and

adequately designed and conducted clinical studies

22. The Silzone products were designed, manufactured and distributed by St. Jude without adequate testing and without adequate warning or notice that the products with Silzone coating were defective, inherently dangerous, and unfit for their intended use as described herein.

23. At all times material herein, Defendant knew or should have known that its Silzone-coated sewing cuffs caused or could cause inadequate and/or improper healing of tissue around the prosthetic device implant, which increased and exacerbated the risk and danger of paravalvular leakage (“**PVL**”) and thromboembolic (“**T/E**”) events in patients in whom products containing such coating had been implanted.

24. Starting in or about the late summer or early fall of 1998, Defendant St. Jude became aware, or had reason to know, that a significant number of explants, paravalvular leaks, and thromboembolic events involving its Silzone product lines had already occurred. Defendant, however, at that time refused to recall the product line, issue timely, fair and balanced warnings, or institute or recommend proper precautionary measures, and continued to refuse doing so until it belatedly decided to withdraw the Silzone product lines on or about January 21, 2000, after the Data Safety Monitoring Board (“**DSMB**”) for the AVERT study recommended suspension of further enrollment in that trial once it learned that data therefrom associated the Silzone valve with a statistically significant increased incidence of explants, often resulting from paravalvular leaks.

25. Prior to the action by the AVERT DSMB, the Medical Device Agency of the United Kingdom in or about November 1999 issued an alert to the United Kingdom’s medical profession and authorities about a high rate of thromboembolic complications associated with St Jude Medical's Silzone (silver coated) mechanical heart valve, particularly among mitral valve patients. The alert further recommended that doctors:

1. Follow up all patients implanted with Silzone® mechanical heart valves to identify any signs of stroke or transient ischemic attack (TIA) and ensure adequate anticoagulation control.

2. Consider examining patients using Trans-[e]sophageal Echocardiography (TOE) to identify any signs of valve thrombus, recognizing that there are certain risks associated with TOE. Priority should be given to patients most likely to be at risk, i.e. those who have suffered thromboembolic complications, those with mitral valve implants, and those who received their implants within the last 6 months.

26. The MDA sought to issue its advisory on Silzone earlier in 1999, but in response to St Jude's objections and lobbying efforts succumbed to its suggestion that the data prompting the advisory (which, in part, had emanated from investigations sponsored by St. Jude) be peer-reviewed by an independent medical society that it had commissioned to review the data before action was taken. That peer review took several months to complete and, when finished, confirmed the validity of the data concerning the thromboembolic danger associated with the Silzone sewing cuffs. The MDA issued the Advisory shortly after it received the report.

27. By the time the product was withdrawn from the market on or about January 21, 2000, approximately 36,000 patients worldwide had been implanted with the Defendant's Master Series heart valve with Silzone. About 14,000 of these were implanted in western European patients.

28. Prior to the introduction of the Silzone products onto the market, SJM neither commissioned nor conducted any carcinogenesis testing on the silver coating, despite its potentially carcinogenic mechanism of action on cell structure.

29. Following the recall numerous medical papers addressing the experience of Silzone patients have been published, including literature from the AVERT study reporting on a significantly increased risk of thromboembolic events associated with Silzone-coated heart valves, particularly those implanted in the mitral position. There have also been a number of medical reports documenting impaired healing and excessive pannus (healing tissue) growth associated with

the implantation of Silzone products, as well as a report of a sarcoma (a cancer) occurring in a Silzone implantee.

30. In or about March 1998, Plaintiff O'Neill underwent valve replacement surgery at Mater Misericordiae Hospital in Dublin, Ireland, during which time a Silzone-coated valve was implanted. That valve developed a paravalvular leak and had to be explanted on December 23, 1998. He was then implanted with another Silzone valve, which valve remains in him to date. By letter from his implanting surgeon dated February 11, 2000, which he received on or about February 14, 2000, Plaintiff was first advised that St. Jude had recalled the Silzone heart valves that were implanted in him.

31. If a Silzone-coated valve is determined by examination, laboratory tests, and echocardiography to be leaking, the patient may have to undergo open heart surgery to explant it and replace it with a non-Silzone-coated valve. Such repeat surgery procedure is extremely complicated and dangerous and is often deferred as long as possible.

32. As a direct and proximate result of Defendant's placing defective Silzone products into the stream of commerce, Plaintiff and the Class identified below require a patient registry and a medical monitoring program that in frequency and content is over and above that which they would ordinarily require by virtue of their heart condition and heart implant, including, but not limited to, proper notification and explanation of the problem and risks of the Silzone cuffs, periodic medical examinations by cardiology specialists for, *inter alia*, leaks, tumors, thrombus, stroke and/or transient ischemic attacks associated with the defective Silzone products, echocardiograms and other testing and preventive screening measures in addition to costs and reasonable attorneys' fees. The data collected under such a monitoring regime is to be independently analyzed in accordance with scientifically sound epidemiological and biostastical protocols and procedures.

33. As a direct and proximate result of Defendant's placing defective Silzone products into the stream of commerce, as well as its other tortious and wrongful conduct and omissions in marketing and promoting Silzone products, Plaintiff O'Neill has suffered personal injury due to the need for the explant surgery occasioned by the paravalvular leakage in his Silzone-cuffed heart valve.

34. Plaintiff O'Neill and members of the Class, require, as a consequence, among other things, notification and creation of a registry, ongoing medical surveillance and analytical epidemiological services, including focused medical research, to address the current ongoing risk and harm they face as a result of having a toxic heavy metal (silver) implanted in or about their hearts that has caused them all to sustain an injury at a sub-cellular, cellular and or/or sub-clinical level, which injury is or may be progressive in nature.

III. CLASS ACTION ALLEGATIONS

35. Plaintiffs bring this class action pursuant to Minn. R. Civ. P. 23 (b) (2) on behalf of a class consisting of:

All persons who, while residing in the original European Economic Union member states (*i.e.*-Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Portugal, Spain, Sweden, the Netherlands, Norway and United Kingdom), had a heart valve replacement and/or repair procedure utilizing a product with a Silzone® coating manufactured, developed, designed, fabricated, sold, distributed or otherwise placed into the stream of commerce by Defendant St. Jude Medical, Inc. and/or its international subsidiaries and/or affiliates and in whom said Silzone product is still implanted, excepting those implantees who are or were officers, directors and employees (and their immediate family members) of the Defendant.

36. Plaintiff O'Neill is a member of the Class he seeks to represent as he has a Silzone valve still implanted and he requires diagnostic and screening tests and procedures over and above that which he would ordinarily require as a result of Defendant's conduct and/or defective product.

Plaintiff O'Neill is also entitled to remedies addressing the economic losses resulting from Defendant's violation of Minnesota consumer protection laws. The subject Class will not be seeking to recover for personal injuries on behalf of absent Class members, and any absent Class member with a present personal injury claim can and should be given reasonable and practical notice of such fact and a right to opt-out from the Class to pursue such claims on an individual basis.

37. The Class consists of between 10,000 to 14,000 people who were implanted with Silzone cuffed products and therefore are so numerous that joinder is impractical.

38. A class action is superior to all other available means for the fair and efficient adjudication of this controversy.

39. Plaintiff's claims are typical of the claims of the recipient Class because Plaintiff O'Neill had a heart valve replacement with a Silzone product in Ireland, which defective and dangerous device remains implanted in his body to date putting him at heightened risk of developing a serious or fatal injury .

40. There are questions of law and fact common to the recipient Class, including, but not limited to:

(a) whether the heart valve replacement and repair products designed, developed, manufactured, distributed, fabricated, supplied, advertised, promoted and/or sold by the Defendant has a defect or defects;

(b) the nature of said defect(s);

(c) whether the heart valve replacement and repair products with Silzone coating are susceptible to an increased risk of paravalvular leakage;

(d) whether the heart valve replacement and repair products with Silzone coating are susceptible to an increased risk of sterile endocarditis;

(e) whether the heart valve replacement and repair products with Silzone coating are susceptible to an increased risk of explant;

(f) whether the heart valve replacement and repair products with Silzone coating are susceptible to causing an increase risk of thromboembolic complications;

(g) when the Defendant knew or should have known that its heart valve replacement and repair products with Silzone coating were susceptible to paravalvular leakage, sterile endocarditis, explant, and/or thromboembolic complications;

(h) whether the heart valve replacement and repair products with Silzone coating are susceptible to causing excessive pannus growth which can interfere with the proper function of the leaflets;

(i) whether the heart valve replacement and repair products with Silzone coating are susceptible to impaired healing and/or lack of tissue ingrowth giving rise to an increased risk of paravalvular leak and/or thromboembolic complications;

(j) whether the Defendant conducted testing on the heart valve replacement and repair products with Silzone coating necessary to determine its safety prior to selling and/or distributing it;

(k) when Defendant conducted such testing, if at all;

(l) whether said testing was adequate and responsible;

(m) whether Defendant accurately reported its test results;

(n) whether Defendant failed to provide adequate warnings concerning its heart valve replacement and repair products with Silzone;

(o) whether the warnings, if any, given by Defendant were reasonable and adequate in light of what it knew or should have known;

(p) whether consumers who were implanted with heart valve replacement and repair products with Silzone coating are at an increased risk of developing serious latent diseases or injuries;

(q) whether monitoring and testing procedures which make early detection and treatment of the serious illnesses caused by silver toxicity, such as a paravalvular leak and/or increased thromboembolic complications, are possible and beneficial;

(r) whether medical monitoring is appropriate;

(s) whether Defendant designed and manufactured heart valve replacement and repair products with Silzone coating that were dangerously defective because they had a tendency to cause paravalvular leakage, sterile endocarditis, explants, thromboembolic complications, excess pannus growth, impaired healing, and/or lack of tissue ingrowth, which could lead to serious adverse health affects;

(t) whether pursuant to the European Product Directive the Silzone products are defective under the European Product Liability Directive as the safety of the product was not such as persons are entitled to expect;

(u) whether Defendant concealed adverse information from Plaintiff O'Neill and the recipient Class, and/or their physicians regarding the testing and safety of the heart valve replacement and repair products with Silzone coating;

(v) what steps, if any, Defendant took to cure or mitigate the defects in the heart valve replacement repair products with Silzone coating after it knew or should have known of the defects and of the injuries and risks associated with their use;

(w) whether Defendant is strictly liable to those injured by their defective heart valve replacement and repair products with Silzone coating;

(x) whether Defendant acted negligently towards Plaintiffs and members of the Class;

(y) whether the heart valve products with Silzone coating were safe for their intended use;

(z) whether Defendant actively concealed defects in the product and the risk of serious injury that could result;

(aa) what is the proper mechanism for assessing and awarding compensation and administering other relief, including relief to reduce the threat of future harm; and/or

(bb) whether Plaintiffs and others similarly situated need and would benefit from a notice and registry program, a medical surveillance program, and/or medical research program designed to address the substantially increased risk of harm to which Defendant's defective products have subjected them;

41. The claims of Plaintiff O'Neill are typical of the claims of the Class he seeks to represent.

42. These and other questions of law and/or fact are common to the Class and predominate over any questions affecting only individual Class members.

43. Plaintiff will fairly and adequately represent and protect the interests of the members of the Class. Plaintiff has retained counsel competent and experienced in complex class actions, toxic tort, products liability and consumer fraud litigation. Plaintiff has no claims antagonistic to those of the members of the recipient Class.

44. Class certification pursuant to Rule 23(b)(1)(A) is appropriate because the prosecution of separate actions creates the risk of inconsistent or varying adjudications with respect

to individual members of the Class which would establish incompatible standards of conduct for the Defendant.

45. Class certification pursuant to Rule 23(b)(1)(B) is appropriate because prosecution of separate actions by individual members of the recipient Class would create a risk of adjudications with respect to individual members of the recipient Class which would, as a practical matter, be dispositive of the interests of the other members not parties to the adjudication or substantially impair or impede their ability to protect their interests.

46. Class certification pursuant to Rule 23(b)(2) is appropriate because Defendant's course of dealing with members of the recipient Class adversely affects all members of the recipient Class thereby making appropriate final injunctive relief, including the creation of a medical monitoring and medical research trust funds as to the Class.

47. Class certification pursuant to Rule 23(b)(3) also is appropriate because common issues of law and fact relative to the effect of the Defendant's products and its course of dealing are common to the members of the Class and said questions of law or fact predominate over any questions affecting only individual members, thereby rendering the class action superior to other available methods for the fair and efficient adjudication of this controversy.

48. No unusual difficulties are likely to be encountered in the management of this action as a class action. The key liability witnesses are located for the most part in Minnesota or are employed by SJM and are under its direction and control.

49. Class certification is also appropriate because Defendant St. Jude, has acted on grounds generally applicable to the Class, making appropriate equitable injunctive relief with respect to Plaintiff and the class members. Specifically, Plaintiff seeks injunctive relief in the form of the creation of a medical monitoring program trust and a medical research program trust.

50. As a direct and proximate result of Defendant's acts and the defective nature of the medical products at issue, members of the Class face an increased susceptibility to injuries as described herein. This irreparable threat to their health can only be fully mitigated by the creation of one or more trust funds under the control and auspices of the Court to provide for appropriate and necessary medical monitoring and medical research, including: locating and notifying the Class of the defects and the potential medical harm; the creation of a registry and a baseline database of Class members; the funding for the periodic monitoring and assessment of the Class members; the researching, gathering and forwarding of epidemiological and treatment/diagnostic modality information to Class members' treating physicians and other health care providers; the researching and assessment of the injuries or complications which are or may result from defects in the subject products, including the recognition and assessment of risks of explant versus no-explant alternatives; the research and development of modalities to aid in the diagnosis and treatment of resulting injuries; and development and implementation of appropriate psychological and emotional support and treatment programs for Class members and their spouses.

51. Plaintiffs O'Neill and the Class have no adequate remedy at law in that monetary damages alone will not compensate for the insidious and continuing nature of the harm to them, and only an appropriate research and medical monitoring program, which notifies and registers the members of the recipient Class and thereafter researches and collects information relating to their problems and risks can prevent the greater harms which may not occur immediately and which may be preventable or remedied if proper research is conducted, programs or treatment protocols developed, and such programs/protocols implemented or made available to Class members before the harm occurs or becomes worse.

IV. SUBSTANTIVE CAUSES OF ACTION

COUNT I

STRICT LIABILITY UNDER THE EUROPEAN PRODUCT DIRECTIVE

52. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows:

53. At all times material hereto, St Jude was a “producer” of the subject Silzone product as set forth in Article 3 §1 of the European Product Directive as (a) it was the actual manufacturer of the Silzone products; (b) it placed its name and registered trademark on the Silzone products; and/or (3) it represented to the public and medical profession that it was the supplier, manufacturer or producer of the subject Silzone products.

54. Under Article 6, § 1 of the European Product Directive, a product distributed in the EU member nations is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including:

- (a) the presentation of the product;
- (b) the use to which it could reasonably be expected that the product would be put;
- (c) the time when the product was put into circulation.

55. At all times material hereto, persons were generally entitled to expect that Silzone products were at least as safe as other prosthetic heart valves in the marketplace, including, but not limited to, St. Jude’s own conventionally cuffed versions of the Silzone products. Silzone products were not as safe as other prosthetic heart valves available in the channels of commerce, including, but not limited to, St. Jude’s non-Silzone-coated versions of the same products.

56. Silzone products did not provide the safety which a person is entitled to expect, taking all circumstances into account, including:

- (a) the presentation of the products;

- (b) the use to which it could reasonably be expected that the products would be put;
- (c) the time when the products were put into circulation.

57. The Silzone products were defective as defined in Article 6, §1 of the European Product Directive.

58. The defective properties of Silzone products proximately caused the personal injury and harm sustained by Plaintiff O'Neill, Spouse Plaintiff, and members of the Class.

WHEREFORE, Plaintiff in his own right and on behalf of the Class, and Spouse Plaintiff in her right, demand judgment against the Defendant for the following relief and remedies:

(a) as to the Class, an Order pursuant to Minn. Rule 23 permitting this action to be maintained as a class action on behalf of the Class as specified herein, appointing Plaintiff as the representative of the Class and Plaintiffs' counsel as counsel for the Class;

(b) as to the Class a judgment and/or decree in favor of Plaintiff and the Class against Defendant creating a trust fund paid for by Defendant which, under Court supervision, will design, pay for and manage the delivery of medical monitoring services, including, but not limited to, testing and preventative screening care of the adverse and latent conditions resulting from, or potentially resulting from, the implantation and use of defective medical products at issue in this suit;

(c) as to the Class a judgment and/or decree in favor of Plaintiff and the Class against Defendant creating a trust fund, paid for by Defendant, under Court supervision, to finance medical research on monitoring services, including, but not limited to, testing and preventative screening care of conditions resulting from, or potentially resulting from, the defective medical products at issue in this suit;

(d) as to the Class a judgment and/or order requiring Defendant to bear the cost of publication to members of the Class and the medical community of advising and educating them of the need for appropriate medical screening and monitoring concerning the medical conditions that are at issue in this suit, the content, form and manner of such publication to be approved by the Court;

(e) as to Plaintiff O'Neill individually for his personal injuries, medical expenses, loss of income and earning capacity, and loss of life's pleasures, including those that occurred in the past, those that presently exist, and those that occur in the future, judgment in favor of Plaintiff awarding all appropriate compensatory damages;

(f) as to Spouse Plaintiff individually for her loss of consortium, services and society of her husband judgment in favor of Spouse Plaintiff awarding all appropriate compensatory damages; and

(g) such further relief as this Court deems necessary, just, and proper.

COUNT II

STRICT LIABILITY UNDER LAW

59. Plaintiffs incorporate all of the allegations set forth above as if fully set forth herein.

60. The heart valve replacement and repair products with Silzone ("Silzone products") manufactured and/or supplied by Defendant St. Jude were defective in design and/or formulation in that when they left the hands of the said Defendant, the foreseeable risks exceeded the benefits associated with the design and/or formulation.

61. Alternatively, the Silzone products supplied by the Defendant were defective in design and/or formulation in that they were more dangerous than an ordinary consumer would expect when used in their intended or reasonably foreseeable manner.

62. The Silzone products manufactured and/or supplied by the Defendant were defective due to inadequate warning or instruction in that, when they left the hands of said Defendant, Defendant knew or should have known that the product was such as to create a risk of harm to consumers, and Defendant failed to exercise reasonable care to warn of said risk.

63. The Silzone products manufactured and/or supplied by the Defendant were defective due to inadequate post-marketing warnings and/or instructions in that when they left the hands of the Defendant, it knew or should have known the risk involved with the use of said product and failed to exercise reasonable care to provide an adequate warning to the users of the product.

64. The Silzone products manufactured and/or supplied by the Defendant were defective in that they failed to conform to the representations of Defendant when they left its hands in that they were not safe for use by consumers.

65. The Silzone products manufactured and/or supplied by the Defendant were defective in that the Defendant failed to adequately test the products before placing them into the stream of commerce.

66. As a direct and proximate result of the defective condition of the Silzone products, as manufactured by the Defendant, Plaintiff, Spouse Plaintiff and members of the Class suffered and will continue to suffer the injuries described above.

WHEREFORE, Plaintiff in his own right and on behalf of the Class, and Spouse Plaintiff in her right, demand judgment against the Defendant for the following relief and remedies:

(a) as to the Class an Order pursuant to Minn. Rule 23 permitting this action to be maintained as a class action on behalf of the Class as specified herein, appointing Plaintiff as the representatives of the Class and Plaintiffs' counsel as counsel for the Class;

(b) as to the Class a judgment and/or decree in favor of Plaintiffs and the Class against Defendant creating a trust fund paid for by Defendant which, under Court supervision, will design, pay for and manage the delivery of medical monitoring services, including, but not limited to, testing and preventative screening care of the adverse and latent conditions resulting from, or potentially resulting from, the implantation and use of defective medical products at issue in this suit;

(c) as to the Class a judgment and/or decree in favor of Plaintiffs and the Class against Defendant creating a trust fund, paid for by Defendants, under Court supervision, to finance medical research on monitoring services, including, but not limited to, testing and preventative screening care of conditions resulting from, or potentially resulting from the defective medical products at issue in this suit;

(d) as to the Class a judgment and/or order requiring Defendant to bear the cost of publication to members of the Class and the medical community of advising and educating them of the need for appropriate medical screening and monitoring concerning the medical conditions that are at issue in this suit, the content, form and manner of such publication to be approved by the Court;

(e) as to Plaintiff O'Neill individually for his personal injuries, medical expenses, loss of income and earning capacity, and loss of life's pleasures, including those that occurred in the past, those that presently exist, and those that occur in the future, judgment in favor of Plaintiffs awarding all appropriate compensatory damages;

(f) as to Spouse plaintiff individually for her loss of consortium, services and society of her husband judgment in favor of Spouse Plaintiff awarding all appropriate compensatory damages; and .

(g) such further relief as this Court deems necessary, just, and proper.

COUNT III
NEGLIGENCE

67. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows:

68. Defendant had a duty to exercise reasonable care in the manufacture, sale, and/or distribution of the subject Silzone products it placed into the stream of commerce, including a duty to assure that the products did not cause users to suffer unreasonable or unnecessary injury, infection or unreasonable, dangerous side effects.

69. Defendant failed to exercise ordinary care in the warning about, design, manufacture, sale, testing, marketing, advertising, promoting and/or distribution into the stream of commerce of subject Silzone medical products in that Defendant knew or should have known that the subject Silzone medical products created a high risk of unreasonable, dangerous paravalvular leakage, valve failure, explant, sterile endocarditis, thromboembolic events, and other side-effects, some of which, e.g., can only be alleviated by open heart surgery or other invasive procedures and some of which, heart failure, impingement of valve leaflets, stroke or embolism, can be fatal.

70. Defendant was negligent in the warning about, design, manufacture, sale, testing, marketing, advertising, promoting and/or distribution of the subject Silzone medical products in that it:

(a) Failed to use due care in designing, developing and manufacturing the Silzone medical products so as to avoid the aforementioned risks to individuals when they were being implanted or used;

(b) Failed to accompany their products with proper warnings regarding all possible adverse risks, effects or injuries associated with the use of the subject Silzone medical products;

(c) Failed to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of the subject Silzone medical products;

(d) Failed to conduct adequate pre-clinical and clinical testing to determine the efficacy of the subject Silzone medical products to prevent or reduce the incidence of prosthetic valve endocarditis;

(e) Failed to provide adequate training to medical care providers for appropriate use or monitoring of the subject Silzone medical products;

(f) Failed to warn Plaintiff and members of the Class who have been implanted with the subject Silzone medical products about the following: (1) the need for comprehensive, greater than regular medical monitoring to ensure early discovery of serious or potentially fatal cardiac, cardiovascular, and/or cerebrovascular side effects; (2) the need for greater INR level monitoring and anti-coagulation adjustments following the implantation of a Silzone product; and/or (3) the possibility of becoming disabled as a result of the subject Silzone medical products and/or having to undergo repeat heart surgery sooner than ordinarily associated with heart valve prosthetic implants;

(g) Failed to test and/or warn adequately about the reaction or interaction of one or more of the component parts in the subject Silzone medical products when implanted in the human body;

(h) Placed an unsafe product into the stream of commerce; and/or

(i) Failed to promptly recall and/or withdraw the Silzone products from the channels of commerce under the circumstances

71. Defendant knew or should have known that consumers such as Plaintiff could foreseeably suffer injury as a result of Defendant's failure to exercise ordinary care as described above.

72. Defendant's negligence was a proximate cause of Plaintiff's and other Class members' suffering a significantly increased risk of serious injury and disease, which they will continue to suffer as previously described, as well as the other injuries sustained by Plaintiff and Spouse Plaintiff described above .

73. As a further result, Plaintiff, Spouse Plaintiff and other Class members may and probably will be required to pay sums to ascertain the existence, nature and extent of their injuries in the future.

WHEREFORE, Plaintiff in his own right and on behalf of the Class, and Spouse Plaintiff in her right, demand judgment against the Defendant for the following relief and remedies:

(a) as to the Class, an Order pursuant to Minn. Rule 23 permitting this action to be maintained as a class action on behalf of the Class as specified herein, appointing Plaintiff as the representative of the Class and Plaintiffs' counsel as counsel for the Class;

(b) as to the Class a judgment and/or decree in favor of Plaintiffs and the Class against Defendant creating a trust fund paid for by Defendant which, under Court supervision, will design, pay for and manage the delivery of medical monitoring services, including, but not limited to, testing and preventative screening care of the adverse and latent conditions resulting from, or potentially resulting from, the implantation and use of defective medical products at issue in this suit;

(c) as to the Class a judgment and/or decree in favor of Plaintiffs and the Class against Defendant creating a trust fund, paid for by Defendant, under Court supervision, to finance medical research on monitoring services, including, but not limited to, testing and preventative screening care of conditions resulting from, or potentially resulting from the defective medical products at issue in this suit;

(d) as to the Class a judgment and/or order requiring Defendant to bear the cost of publication to members of the Class and the medical community of advising and educating them of the need for appropriate medical screening and monitoring concerning the medical conditions that are at issue in this suit, the content, form and manner of such publication to be approved by the Court;

(e) as to Plaintiff O'Neill individually for his personal injuries, medical expenses, loss of income and earning capacity, and loss of life's pleasures, including those that occurred in the past, those that presently exist, and those that occur in the future, judgment in favor of Plaintiff awarding all appropriate compensatory damages;

(f) as to Spouse plaintiff individually for her loss of consortium, services and society of her husband judgment in favor of Spouse Plaintiff awarding all appropriate compensatory damages; and

(g) such further relief as this Court deems necessary, just, and proper.

COUNT V

VIOLATION OF THE FALSE ADVERTISING ACT, THE CONSUMER FRAUD ACT, THE UNLAWFUL TRADE PRACTICES ACT AND THE UNIFORM DECEPTIVE TRADE PRACTICES ACT

74. Plaintiffs incorporates by reference all preceding paragraphs as if fully set forth herein and further allege as follows:

75. By reason of the conduct as alleged herein, and by inducing Plaintiff and his physicians to use Silzone heart valves through the use of false and/or misleading advertising, representations and statements, Defendant violated the provisions of the Minnesota Statutes Section 325F.07, 325F.69 and 325D.44.

76. As a direct and proximate result of Defendant's statutory violations, Plaintiff was implanted with the Silzone heart valves which would not have occurred had Defendant not issued false and/or misleading advertising, representations and statements to induce the Plaintiff and his physicians to use the product.

77. By reason of such violations and pursuant to Minnesota Statutes Section 8.31, subdivision 3a, Section 325D.44, Section 325F.67 and Sections 325F.68-70, Plaintiff and the Class are entitled to recover all of the monies paid for the product; to be compensated for the cost of the medical care arising out of the use of the product, together with any and all consequential damages recoverable under the law, including, but not limited to, both past and future medical expenses, past wage loss, loss of future earning capacity, past and future pain, suffering, disability and emotional distress.

78. In addition, pursuant to Minnesota Statutes Section 8.31, Plaintiff and the Class are entitled to recover costs and disbursements, including costs of investigation and reasonable attorneys' fees, and any other equitable relief as deemed by this Court.

WHEREFORE, Plaintiff in his own right and on behalf of the Class, and Spouse Plaintiff in her right, demand judgment against the Defendant for the following relief and remedies:

(a) as to the Class, an Order pursuant to Minn. Rule 23 permitting this action to be maintained as a class action on behalf of the Class as specified herein, appointing Plaintiff as the representatives of the Class and Plaintiffs' counsel as counsel for the Class;

(b) as to the Class a judgment and/or decree in favor of Plaintiff and the Class against Defendant creating a trust fund paid for by Defendant which, under Court supervision, will design, pay for and manage the delivery of medical monitoring services, including, but not limited to, testing and preventative screening care of the adverse and latent conditions resulting from, or potentially resulting from, the implantation and use of defective medical products at issue in this suit;

(c) as to the Class a judgment and/or decree in favor of Plaintiff and the Class against Defendant creating a trust fund, paid for by Defendant, under Court supervision, to finance medical research on monitoring services, including, but not limited to, testing and preventative screening care of conditions resulting from, or potentially resulting from the defective medical products at issue in this suit;

(d) as to the Class a judgment and/or order requiring Defendant to bear the cost of publication to members of the Class and the medical community of advising and educating them of the need for appropriate medical screening and monitoring concerning the medical conditions that are at issue in this suit, the content, form and manner of such publication to be approved by the Court;

(e) as to the Class a judgment and/or order requiring Defendant to make restitution of the costs of the Silzone Products and the costs of implant and explant surgery relating

to the defective Silzone Product, and the costs of diagnostic and treatment services associated with the defective product.

(f) as to Plaintiff O'Neill individually for his personal injuries, medical expenses, loss of income and earning capacity, and loss of life's pleasures, including those that occurred in the past, those that presently exist, and those that occur in the future, judgment in favor of Plaintiff awarding all appropriate compensatory damages;

(g) as to Spouse plaintiff individually for her loss of consortium, services and society of her husband judgment in favor of Spouse Plaintiff awarding all appropriate compensatory damages; and

(h) such further relief as this Court deems necessary, just, and proper.

JURY DEMAND

Plaintiffs demand a trial by jury on those issues so triable.

ZIMMERMAN REED

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