UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: INTER - OP™ HIP PROSTHESIS LIABILITY LITIGATION	:	MDL Docket No. 01-CV-9000 (Judge Kathleen O'Malley)
This Document Relates to All Cases	:	

PLAINTIFFS' AMENDED AND CONSOLIDATED CLASS ACTION COMPLAINT

Plaintiffs, through counsel, for their Amended and Consolidated Class Action Complaint (the "Amended Complaint") against the Defendants, state as follows:

NATURE OF CLAIM

1. On December 5, 2000, Defendant Sulzer Orthopedics, Inc. announced the voluntary recall of certain Inter-Op™ acetabular shells used in total hip prosthesis. (Affected Inter-Op™ shells"). Plaintiffs bring this action pursuant to Rule 23 of the Federal Rules of Civil Procedure, on their own behalf and as representatives of a class consisting of all citizens or residents of the United States who have had Affected Inter-Op™ acetabular shell hip implants placed in their bodies (the "Class"), or their estates, administrators or other legal representatives, heirs or beneficiaries, and any other person asserting the right to sue independently or derivatively, and two subclasses. Subclass 1

consists of those Class members who have had Affected Inter-Op™ shells placed into their bodies and have already undergone revision surgery prior to the Final Judicial Approval Date and Subclass 2 consists of Class members who may need to undergo revision surgery after the Final Judicial Approval Date to correct problems with the Affected Inter-Op™ shells.

2. Plaintiffs bring this action individually and as class and subclass representatives to recover damages, restitution, refunds, loss of consortium and/or for equitable, injunctive and declaratory relief against Defendants Sulzer Medica, Ltd., Sulzer Orthopedics, Inc. and Sulzer Orthopedics, Ltd.

3. Defendants placed Inter-Op™ acetabular shells into the stream of worldwide commerce and interstate commerce in the United States. It did so without adequate testing and with no warning that the Inter-Op™ acetabular shells were defective, inherently dangerous and unfit for their intended use as described herein.

4. As a direct and proximate result of the defective products placed into the stream of commerce by Defendants, Plaintiffs are members of the Class and of the subclasses (as defined in paragraph 1) and suffered and continue to suffer severe injury and disability, including physical and mental pain and suffering, and will continue to experience such injuries in the indefinite future.

5. Plaintiffs and members of the Class and subclasses have incurred significant medical, hospital, rehabilitative and/or pharmaceutical expense and/or lost wages and will continue to incur such expenses and losses in the future.

PARTIES

6. Plaintiff, Harlan Herman "(Herman)", is and at all relevant times was a resident and citizen of the City of Northfield, County of Summit, State of Ohio. On or about March 8, 2000, Plaintiff Herman was implanted with an artificial hip utilizing an Affected Inter-Op™ shell and has not undergone a revision surgery to replace the Inter-Op™ shell.

7. Brenda Herman is the wife of Harlan Herman and at all relevant time is and was a resident and citizen of the City of Northfield, County of Summit, State of Ohio.

8. Plaintiff Linda F. Wells, is and was a resident of University Heights, County of Cuyahoga, State of Ohio. In February 2000, Plaintiff Wells was implanted with an artificial hip utilizing an Affected Inter-Op™ shell and has not undergone a revision surgery to replace the Affected Inter-Op™ shell.

9. Plaintiff George L. Yasenchack "(Yasenchack)" at all relevant times is and was a resident and citizen of the City of Berea, County of Cuyahoga, State of Ohio. On or about March 14, 2000, Plaintiff Yasenchack was implanted with an artificial hip utilizing an Affected Inter-Op™ acetabular shell. On April 9, 2001, Yasenchack underwent revision surgery to correct problems he was experiencing with the Affected Inter-Op™ acetabular shell implanted in his body.

10. Mary Jean Yasenchack is the wife of George Yasenchack and at all relevant times is and was a resident and citizen of the City of Berea, County of Cuyahoga, State of Ohio.

11. Defendant Sulzer Medica, Ltd. is a publicly traded company which designs,

manufactures and markets implantable medical devices and biological products for cardiovascular and orthopedic markets worldwide.

12. Defendant Sulzer Medica, Ltd. is the parent company of Defendants Sulzer Orthopedics, Ltd. and Sulzer Orthopedics, Inc. and its principal place of business is in Winterthur, Switzerland.

13. Defendant Sulzer Orthopedics, Inc. is a company in the business of designing, manufacturing and distributing orthopedic devices and its principal place of business is Austin, Texas.

14. Defendant Sulzer Orthopedics, Ltd. is a company in the business of designing, manufacturing and distributing orthopedic devices and its principal place of business is Baar, Switzerland.

15. Defendants, at all times relevant to the claims in this action, designed and/or manufactured and/or supplied and/or distributed and/or sold and/or otherwise placed into the stream of worldwide trade or commerce hip implants with Inter-Op™ acetabular shells.

JURISDICTION AND VENUE

16. Plaintiffs allege an amount in controversy in excess of Seventy-Five Thousand Dollars ($75,000.00), each exclusive of interests and costs.

17. This Court has jurisdiction over this action pursuant to 28 U.S.C. §1332 because the amount in controversy exceeds Seventy-Five Thousand Dollars ($75,000.00) for each Plaintiff and because there is complete diversity of citizenship between Plaintiffs and Defendants.

CLASS ACTION ALLEGATIONS

18. Plaintiffs bring this class action pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), and 23(b)(3) on behalf of a general class (the "Class") consisting of:

> All citizens or residents of the United States who have had Affected Inter-Op™ acetabular shell hip implants placed in their bodies.

19. Plaintiffs also being this action on behalf of two subclasses. Subclass 1 consists of those Class members who have had Affected Inter-Op™ shells placed into their bodies and have already undergone revision surgery prior to the Final Judicial Approval Date to correct problems with the Affected Inter-Op™ shells. Subclass 2 consists of Class members who may need to undergo revision surgery after the Final Judicial Approval Date to correct problems with the Affected Inter-Op™ shells.

20. Plaintiff George Yasenchack brings this action as representative of and on behalf of Subclass 1.

21. Plaintiffs Harlan Herman and Linda Wells bring this action as representatives of and on behalf of Subclass 2.

22. Plaintiffs are all members of the Class and subclasses they seek to represent.

23. The Class and subclasses consist of thousands of members and therefore is so numerous that joinder is impractical.

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

25. Plaintiffs' claims are typical of the claims of the Class and subclasses because they and all the Class Members and subclass members sustained damages which arose from Defendants' wrongful conduct complained of herein.

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

a. Whether the Inter-Op™ acetabular shells designed, developed, manufactured, distributed, fabricated, supplied, advertised, promoted and/or sold by Defendants had a defect(s);

b. The nature of said defect(s);

c. Whether the Inter-Op™ acetabular shells are susceptible to unreasonable failure rates;

d. When Defendants knew or should have known that their Inter-Op™ acetabular shells were susceptible to unreasonable failure rates;

e. Whether Defendants conducted testing on the Inter-Op™ acetabular shells necessary to determine its safety prior to selling and/or distributing it;

f. When Defendants conducted such testing, if at all;

g. Whether said testing was adequate and responsible;

h. Whether Defendants accurately reported test results;

i. Whether Defendants failed to provide adequate warnings concerning the Inter-Op™ acetabular shells;

j. Whether the Inter-Op™ acetabular shells are unreasonably dangerous;

k. Whether the Defendants were negligent in selling the Inter-Op™ acetabular shells without adequate testing or warning;

l. Whether the warnings, if any, given by Defendants were reasonable in light of what they knew or should have known;

m. Whether Defendants' failure to give adequate and timely warning of the dangers of the Inter-Op™ acetabular shells constitutes negligence per se;

n. Whether Defendants breached express or implied warranties in conjunction with the design, development, manufacture, fabrication, marketing, sale and distribution of the Inter-Op™ acetabular shells;

o. Whether Defendants concealed adverse information from Plaintiffs and the Class and subclasses regarding the testing and safety of the Inter-Op™ acetabular shells ;

p. What steps, if any, Defendants took to cure the defects in the Inter-Op™ acetabular shells after they knew of the defects and of the injuries and risk associated with their use;

q. Whether Defendants are strictly liable to those injured by their defective Inter-Op™ acetabular shells;

r. Whether the Inter-Op™ acetabular shells were of merchantable quality and safe for their intended use;

s. Whether Defendants made any express representations about the Inter-Op™ acetabular shells;

t. Whether Defendants' manufacturing process was negligent;

u. Whether Defendants actively concealed the defects in the product and the risk of serious injury that could result;

v. What is the proper mechanism for assessing and awarding damages and administering other relief, including relief to reduce the threat of future harm.

27. The claims of Plaintiffs are typical of the claims of the Class and subclasses.

28. Plaintiffs will fairly and adequately represent and protect the interests

of the members of the Class and subclasses. Plaintiffs have retained counsel competent and experienced in complex class actions, toxic tort and products liability litigation. Plaintiffs have no claims antagonistic to those of the Class. Class counsel will consist of Stanley Chesley of the law firm of Waite, Schneider, Bayless & Chesley, John Climaco of the law firm of Climaco, Lefkowitz, Peca, Wilcox & Garofoli, Don Barrett of the Barrett law office. and Keith Fleischman of the law firm of Millberg Weiss Bershad Hynes & Lerach. Each of the subclasses will be represented by separate counsel. Subclass 1 members will be represented by R. Eric Kennedy of the law firm of Weiseman Goldberg and Weisman. Subclass 2 members will be represented by Richard S. Wayne of the law firm of Strauss & Troy.

29. Class certification pursuant to Rule 23(b)(2) is appropriate because Defendants' course of dealing with members of the Class adversely affects all members of the Class, thereby making appropriate final and injunctive relief corresponding to declaratory relief with respect to the Class as a whole, whereby the Defendants would be compelled to cease such course of dealing.

30. Class certification pursuant to Rule 23(b)(3) is appropriate because common issues of law and fact relative to the effect of the Defendants' 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.

FACTUAL BACKGROUND

31. Hip implants, also called hip prosthesis, are used to treat disorders of the hip joint by surgically replacing the patient's natural hip.

32. Defendants designed, manufactured and distributed hip implants which included acetabular shells trademarked as "Inter-Op™ acetabular shells".

33. In excess of 17,500 Inter-Op™ acetabular shells were implanted since July, 1997.

34. On December 8, 2000, Sulzer Medica announced that Sulzer Orthopedics voluntarily recalled certain manufacturing lots of the Inter-Op™ acetabular shells. The announcement stated that "[s]ince mid-September, 2000 Sulzer Orthopedics has received reports of post-operative loosening of a number of the Inter-Op™ acetabular shells." Basing their computation on 17,500 products from the affected lots having been implanted, 61 cases of loosening were reported or less than .5% of the total number of implanted shells.

35. According to the Sulzer Medica announcement, approximately 90% of the affected lots were implanted in the United States.

36. According to the Sulzer Medica announcement, the post operative loosening appears "to be related to a reaction of the body to a slight residue of lubricant used in the manufacturing process" and that "[b]ased on a random sampling of affected product lots, a small number of products evidenced a higher than expected level of this residue."

37. As a direct and proximate result of the defective product being placed

into the stream of commerce by the Defendants, Plaintiffs and members of the Class and subclasses suffered and will continue to suffer possible death, severe injury and disability including physical and mental pain and suffering and will continue to experience such injuries into the future.

38. Plaintiffs and members of the Class have incurred significant medical, hospital and/or pharmaceutical expenses and lost wages and will continue to incur such expenses in the future.

FIRST CAUSE OF ACTION
Strict Liability

39. Plaintiffs restate the allegations set forth in Paragraphs 1 through 39 of their Amended Complaint as if fully rewritten herein.

40. The Inter-Op™ acetabular shells manufactured and/or supplied by Defendants were defective in manufacture or construction in that, when they left the hands of said Defendants, they deviated in a material way from their manufacturing performance standards and/or they differed from otherwise identical units manufactured to the same design formula.

41. The Inter-Op™ acetabular shells manufactured and/or supplied by Defendants were defective in design and/or formulation in that, when they left the hands of said Defendants, the foreseeable risks exceeded the benefits associated with the design and/or formulation.

42. Alternatively, the Inter-Op™ acetabular shells supplied by Defendants 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.

43. The Inter-Op™ acetabular shells manufactured and/or supplied by said Defendants were defective due to inadequate warning or instruction in that, when they left the hands of said Defendants, they knew or should have known that the product was such as to create a risk of harm to consumers and Defendants failed to exercise reasonable care to warn of said risk.

44. The Inter-Op™ acetabular shells manufactured and/or supplied by said Defendants were defective due to inadequate post-marketing warnings and/or instructions in that, when they left the hands of Defendants, they 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 users of the product.

45. The Inter-Op™ acetabular shells manufactured and/or supplied by said Defendants were defective in that they did not conform to the representations of Defendants, when they left their hands, that they were safe for use by consumers.

46. As a direct and proximate result of the defective condition of the Inter-Op™ acetabular shells, as manufactured by the said Defendants, Plaintiffs and members of the Class and subclasses, and their spouses, suffered and will continue to risk possible death and suffer injury, disability, expense and economic loss as previously described. Defendants are strictly liable for said damages.

SECOND CAUSE OF ACTION
Negligence

47. Plaintiffs restate the allegations set forth in Paragraphs 1 through 47 of their Amended Complaint as if fully rewritten herein.

48. Defendants had a duty to exercise reasonable care in the manufacture, design and/or supply of the Inter-Op™ acetabular shells into the stream of worldwide commerce, including a duty to exercise care to assure that the products were safe for their intended use by consumers. Defendants maliciously, recklessly and/or negligently failed to exercise ordinary care in the manufacture, testing, design and/or supply of the Inter-Op™ acetabular shells into the stream of worldwide commerce.

49. Defendants maliciously, recklessly and/or negligently failed in their duty to exercise reasonable care in the provision of an adequate warning as to the risks of the Inter-Op™ acetabular shells that they knew or should have known.

50. Defendants maliciously, recklessly and/or negligently failed to exercise reasonable care in the post-marketing warnings as to the risks of the Inter-Op™ acetabular shells when they knew or should have known of said risks.

51. As a direct and proximate result of Defendants' malicious, reckless and/or negligent conduct, Plaintiffs and members of the Class and subclasses, including spouses, suffered and will continue to risk possible death and suffer injury, disability, expense, harm, and economic loss as previously described rendering Defendants liable for punitive as well as compensatory damages.

THIRD CAUSE OF ACTION
Breach of Implied Warranty

52. Plaintiffs restate the allegations set forth in Paragraphs 1 through 52 of their Amended Complaint as if fully rewritten herein.

53. Defendants are in the business of manufacturing and/or supplying and/or placing into the stream of commerce Inter-Op™ acetabular shells for consumers.

54. By placing Inter-Op™ acetabular shells in to the stream of commerce, said Defendants impliedly warranted that the Inter-Op™ acetabular shells were fit and safe for their intended use.

55. The Inter-Op™ acetabular shells placed into the stream of commerce by said Defendants were defective in that they were not fit and safe for their intended use.

56. The defect in the Inter-Op™ acetabular shells manufactured and/or supplied by said Defendants was present at the time the product left the hands of said Defendants.

57. Defendants breached the implied warranty for the Inter-Op™ acetabular shells because said products were defective, unmerchantable and not fit for their intended purpose.

58. Plaintiffs and members of the Class and subclasses were foreseeable users of the Inter-Op™ acetabular shells.

59. As a direct and proximate result of Defendants' breach of implied

warranty, Plaintiffs and members of the Class and subclasses, including spouses, suffered and will continue to risk possible death and suffer injury, disability, expense and economic loss as previously described.

FOURTH CAUSE OF ACTION
Breach of Express Warranty

60. Plaintiffs restate the allegations set forth in Paragraphs 1 through 60 of their Amended Complaint as if fully rewritten herein.

61. Defendants expressly warranted to Plaintiffs and the Class and subclasses that the Inter-Op™ acetabular shells, which they designed, developed, manufactured and sold to Plaintiffs and the Class and subclasses, were of merchantable quality, fit and safe and otherwise not injurious to the Plaintiff's health and well being.

62. The Inter-Op™ acetabular shells implanted in Plaintiffs and the Class and subclasses were unsafe, unmerchantable, unfit for use in the body, and otherwise injurious to Plaintiffs and the Class and subclasses.

63. Through their sale of Inter-Op™ acetabular shells, Defendants were merchants pursuant to Section 2-314 of the Uniform Commercial Code.

64. Defendants breached express warranties of merchantability in the sale of Inter-Op™ acetabular shells to Plaintiffs and the Class and subclasses in that said products were not fit for their ordinary purposes described above.

65. As a direct and proximate result of Defendants' breach of their express warranties as described herein, Plaintiffs and the Class and subclasses,

including spouses, were caused to risk possible death and suffer substantial and severe harm, injury, and damage.

FIFTH CAUSE OF ACTION
Fear of Future Product Failure

66. Plaintiffs restate the allegations set forth in Paragraphs 1 through 66 of their Amended Complaint as if fully rewritten herein.

67. Defendants placed into the stream of commerce defective Inter-Op™ acetabular shells knowing that said products were not fit for their intended purposes and knowing that said products caused attendant medical problems as described herein.

68. Defendants knew that Plaintiffs and the Class and subclasses would suffer mental distress and anxiety upon learning that said Inter-Op™ acetabular shells possessed a likelihood of failure and the development of attendant medical problems as described herein, thereby causing serious bodily injury or possible death.

69. Defendants' conduct in manufacturing, distributing, wholesaling, fabricating, advertising, promoting, modifying, and placing on the market and into the stream of commerce known defective products has directly and proximately caused Plaintiffs and the Class and subclasses to suffer mental distress and anxiety because of the fear of knowing that there is a likelihood that the Inter-Op™ acetabular shells will fail in the future, causing attendant medical problems as described herein.

SIXTH CAUSE OF ACTION
Misrepresentation

70. Plaintiffs restate the allegations set forth in Paragraphs 1 through 70 of their Amended Complaint as if fully rewritten herein.

71. Defendants negligently and carelessly made the foregoing misrepresentations without a reasonable basis thereto and did not possess information on which to accurately base those representations.

72. Defendants were aware that they did not possess information on which to accurately base the foregoing representations and concealed from Plaintiffs and the Class and subclasses that there was no reasonable basis for making said representation herein.

73. When Defendants made the foregoing representations, they knew or should have known them to be false.

74. In reliance upon the foregoing misrepresentations by the Defendants, Plaintiffs Herman, Iacovone and Yasenchack and the Class were induced to and did subject themselves to the use of the aforementioned products. If Plaintiffs and the Class had known of the true facts, they would not have taken such action and risk. The reliance of Plaintiffs and the Class and subclasses on Defendants' misrepresentations and omissions were reasonable because said representations were made by individuals and entities who are in a position to know the true facts.

75. As a result of the foregoing negligent misrepresentations by Defendants, Plaintiffs and the Class and subclasses suffered injuries and damages

as alleged herein.

SEVENTH CAUSE OF ACTION
Equitable Relief - Medical Monitoring Program

76. Plaintiffs restate the allegations set forth in Paragraphs 1 through 76 of their Amended Complaint as if fully rewritten herein.

77. As a direct and proximate result of Defendants' acts, Plaintiffs and the Class face an increased susceptibility to injuries as described herein. This irreparable threat to their health can only be mitigated by the creation of a medical monitoring fund to provide for a medical monitoring program, including: notifying Plaintiffs and the Class and subclasses of the defects and the potential medical harm; funding of a program for the surgical removal of the Inter-Op™ acetabular shells; funding a study of the long term effects of the Inter-Op™ acetabular shells within the body of Plaintiffs and the Class; gathering and forwarding to treating physicians information relating to the diagnosis and treatment of injuries which may result from the product; aiding in the early diagnosis and treatment of resulting injuries; and providing funding for diagnosis and preventable medical treatment, particularly radiological monitoring and for the surgical removal of the defective Inter-Op™ acetabular shells.

78. Plaintiffs have no adequate remedy in law in that monetary damages alone do not compensate for the insidious and continuing nature of the harm to them, and only a medical monitoring program which notifies Plaintiffs and the Class and subclasses and aids in correcting the problems can prevent the greater harms

which may not occur immediately and which may be preventable, if proper research is conducted and the health risks are diagnosed and treated before they occur or become worse.

79. Plaintiffs and the Class have suffered irreparable harm as alleged herein and, in the absence of equitable relief, Plaintiffs and the Class will suffer further irreparable harm such as death and severe and debilitating injuries from continued retention of the defective Inter-Op™ acetabular shells. Without a medical monitoring program, Plaintiffs and the Class and subclasses might not receive prompt medical care which could prolong their productive lives, increase prospects for improvement and minimize disability.

EIGHTH CAUSE OF ACTION
Punitive Damages

80. Plaintiffs restate the allegations set forth in Paragraphs 1 through 80 of their Amended and Consolidated Complaint as if fully rewritten herein.

81. Defendants' acts were willful and malicious in that Defendants' conduct was carried on with a conscious disregard for the safety and rights of Plaintiffs and the Class and subclasses. Defendants' unconscionable conduct thereby warrants an assessment of exemplary and punitive damages against Defendants in an amount appropriate to punish Defendants and set an example.

WHEREFORE, Plaintiffs, individually and on behalf of the Class and subclasses, pray for judgment against Defendants, jointly and/or severally, as follows:

a. For general damages in an amount to be proven at the time of trial;

b. For special damages in an amount to be proven at the time of trial;

c. For exemplary and punitive damages in an amount to be proven at the time of trial, and sufficient to punish Defendants or to deter them and others from repeating the injurious conduct alleged herein;

d. For pre-judgment and post-judgment interest on the above general and special damages;

e. For restitution and disgorgement of profits;

f. For costs of this suit and attorneys' fees; and

g. All other relief that Plaintiffs, the Class and subclasses may be entitled to at equity or at law, including but not limited to the funding of a medical monitoring program.

JURY DEMAND

Pursuant to Rule 38(b), Federal Rules of Civil Procedure, Plaintiffs and the Class and sublcasses hereby demand a trial by jury.

Dated: August 15, 2001

Respectfully submitted,

Stanley M. Chesley w/c REK

Stanley M. Chesley, Esq. (0000852)
WAITE, SCHNEIDER, BAYLESS & CHESLEY CO., L.P.A.
1513 PNC Tower
Fourth & Vine Street
Cincinnati, OH 45202

Interim Co-Lead Counsel
Proposed Class Counsel

John R. Climaco w/c REK

John R.Climaco, Esq. (0006174)
CLIMACO, LEFKOWITZ, PECA, WILCOX & GAROFOLI CO., L.P.A.
Ninth Floor, The Halle Building
1228 Euclid Avenue
Cleveland, OH 44115

Interim Co-Lead Counsel
Proposed Class Counsel

R. Eric Kennedy, Esq. (0006174)
WEISMAN GOLDBERG & WEISMAN
CO., L.P.A.
1600 Midland Building
Landmark Office Towers
Cleveland, Ohio 44115

Interim Co-Lead Counsel/Liason Counsel
Proposed Counsel for Subclass 1

Donald Barrett w/c REK
Donald Barrett, Esq.
BARRETT LAW OFFICE, P.A.
404 Court Square North
Post Office Box 987
Lexington, Mississippi 39095

Proposed Class Counsel

Keith M. Fleischman w/c REK
Keith M. Fleischman, Esq.
MILBERG WEISS BERSHAD HYNES
& LERACH, LLP
One Pennsylvania Plaza
New York, New York 10119-0165

Proposed Class Counsel

Richard S. Wayne, Esq. (0022390)
STRAUSS & TROY
The Federal Reserve Building
150 East Fourth Street
Cincinnati, Ohio 45202-4018
(513) 621-2120

Proposed Counsel for Subclass 2

CERTIFICATE OF SERVICE

A copy of the foregoing Amended and Consolidated Class Action Complaint has been mailed via regular U.S. Mail on this 15th day of August, 2001, sent Electronically via e-mail and sent via facsimile to the counsel of record identified on the following listing.

R. Eric Kennedy / w/c 08

R. Eric Kennedy, Esq. (0006174)
WEISMAN GOLDBERG & WEISMAN
CO., L.P.A.