AMENDED THIS Sept. 20/2022 PURSUANT TO
MODIFIÉ CE CONFORMÉMENT À
☒ RULE/LA RÈGLE 26.02 (C)
☒ THE ORDER OF AJ PAUL PERELL
L'ORDONNANCE DU
DATED / FAIT LE JULY 22 2022
A. John
REGISTRAR GREFFIER
SUPERIOR COURT OF JUSTICE COUR SUPÉRIEURE DE JUSTICE

Court File No. CV-14-499297

ONTARIO
SUPERIOR COURT OF JUSTICE

B E T W E E N:

ALAN CHAMBERLAIN, TONY KINNEY, PIERRE MARCHAND and LORRIE CHAMBERLAIN

Plaintiffs

-and-

WRIGHT MEDICAL TECHNOLOGY CANADA LTD., WRIGHT MEDICAL TECHNOLOGY, INC., WRIGHT MEDICAL GROUP, INC., MICROPORT MEDICAL B.V. and MICROPORT SCIENTIFIC CORPORATION

Defendants

Proceeding under the *Class Proceedings Act 1992*

FRESH AS AMENDED STATEMENT OF CLAIM

TO THE DEFENDANTS

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the plaintiffs. The claim made against you is set out in the following pages.

IF YOU WISH TO DEFEND THIS PROCEEDING, you or an Ontario lawyer acting for you must prepare a statement of defence in Form 18A prescribed by the Rules of Civil Procedure, serve it on the plaintiff's lawyer or, where the plaintiffs do not have a lawyer, serve it on the plaintiffs, and file it, with proof of service, in this court office, WITHIN TWENTY DAYS after this statement of claim is served on you, if you are served in Ontario.

If you are served in another province or territory of Canada or in the United States of America, the period for serving and filing your statement of defence is forty days. If you are served outside Canada and the United States of America, the period is sixty days.

Instead of serving and filing a statement of defence, you may serve and file a notice of intent to defend in Form 18B prescribed by the Rules of Civil Procedure. This will entitle you to ten more days within which to serve and file your statement of defence

IF YOU FAIL TO DEFEND THIS PROCEEDING, JUDGMENT MAY BE GIVEN AGAINST YOU IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU.

IF YOU WISH TO DEFEND THIS PROCEEDING BUT ARE UNABLE TO PAY LEGAL FEES, LEGAL AID MAY BE AVAILABLE TO YOU BY CONTACTING A LOCAL LEGAL AID OFFICE.

Date Feb. 27/2014 Issued by "S. Desouza"
Local registrar

Address of court office: 393 University Avenue
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CLAIM

1. The Plaintiffs, Alan Chamberlain ("Alan"), Tony Kinney ("Tony"), Pierre Marchand ("Pierre") and Lorrie Chamberlain ("Lorrie") claim on their own behalf and on behalf of all members of the class of persons *described infra* at paragraph 24 (the "Class" or "Class Members") for:

a) an order certifying this action as a class proceeding and appointing Alan, Tony, Pierre, and Lorrie as the Representative Plaintiffs for the Class, pursuant to the *Class Proceedings Act, 1992,* S.O. 1992, c.6 ("CPA");

b) a declaration that the Defendants, as described *infra* at paragraph 13, were negligent in the design, development, testing, manufacturing, licensing, assembly, distribution, marketing and sale of the Wright Medical Conserve Hip System ("Conserve Hip System"). The Conserve family of products includes the Conserve Total A-Class Hip System and the Conserve Plus Total Resurfacing Hip System.

c) a declaration that the Defendants breached their duty to warn the Plaintiffs and other Class Members about defects in the Conserve Hip System;

d) a declaration that the Defendants breached their implied warranties relating to the defective Conserve Hip System;

e) general damages for pain and suffering and mental anguish in the amount of $100,000,000.00 or such different amount as may be proved at trial;

f) special damages on account of, among other things, loss of income, medical and other expenses for testing, treatment and medical monitoring whether incurred by Class Members or a public health insurer, pursuant to all subrogated and/or direct rights of recovery, the particulars of which will be provided to the Defendants prior to trial, or in such an amount as may be proved at trial;

g) punitive damages in the amount of $50,000,000.00, or such other amount as this Honourable Court finds appropriate,

h) alternatively, a declaration that Alan, Tony, Pierre and other Class Members are entitled to recover under restitutionary principles and an accounting and an order requiring the disgorgement of all gross revenue or income or a percent of the sale revenue received by one or all of the Defendants from the sale of the Conserve Hip System in Canada;

i) the costs of notice and administering the plan of distribution of the recovery in this action plus applicable taxes pursuant to s.26(9) of the CPA;

j) an order directing a reference or such other directions as may be necessary to determine issues not determined at the trial of the common issues

k) pre-judgment interest on the damages in accordance with the provisions of the *Courts of Justice Act*, R.S.O. 1990, c. C.43, as amended;

l) post-judgment interest on the damages and costs awarded from the date of judgment herein to the date of payment in accordance with the provisions of the *Courts of Justice Act,* R.S.O. 1990, c. C.43, as amended;

m) costs of this action on a substantial indemnity basis, together with applicable taxes thereon; and

n) such further and other relief as this Honourable Court may deem just.

2. The Plaintiff, Lorrie claims on her own behalf and on behalf of all other members of the class of persons described *infra* at paragraph 25 (the "Family Class" or "Family Class Members") for:

a) an order certifying this action as a class proceeding and appointing her as the representative for the Family Class pursuant to the *Class Proceedings Act, 1992* ("CPA");

b) damages pursuant to the *Family Law Act*, R.S.O. 1990 c. F-3 (*"FLA"*), and other similar provincial legislation, in the amount of $25,000,000.00;

c) special damages in an amount to be provided to the Defendants prior to trial or in such amount as may be determined at trial;

d) pre-judgment interest on the damages in accordance with the provisions of the *Courts of Justice Act*, R.S.O. 1990, c. C.43, as amended;

e) post-judgment interest on the damages and costs awarded from the date of judgment herein to the date of payment in accordance with the provisions of the *Courts of Justice Act,* R.S.O. 1990, c. C.43, as amended;

f) costs of this action on a substantial indemnity basis, together with applicable taxes thereon; and,

g) such further and other relief as this Honourable Court may deem just.

Nature of the Action

3. This action concerns the Defendants' negligent design, testing, development, manufacture, assembly, licensing, marketing, distribution, and sale of the Conserve Hip System. The Conserve Hip System is a metal-on-metal hip resurfacing system designed, manufactured, and distributed by the Defendants for use in patients requiring replacement of the hip joint with a prosthetic implant. The Conserve family of products includes the Conserve Total-A Class Hip System and the Conserve Plus Total Resurfacing Hip System ("Conserve Plus"). The Conserve Total A-Class Hip System and the Conserve Plus are virtually identical. The bearing surface, femoral head components, and surgical technique are identical. Both will perform the exact same way when implanted in a patient. The sole difference between the two devices is the metal "cup" (acetabular component) thickness. The cup component in the Conserve Total A-Class Hip System is 10 millimetres thick, while the cup component in the Conserve Plus Total Resurfacing Hip System is 5 millimetres thick.

4. The Plaintiff Alan underwent hip resurfacing surgery on March 8, 2010 on his right hip and on January 27, 2011 on his left hip. He was implanted with a Conserve Hip System, specifically a Conserve Plus in both hips. He experienced extreme pain within three months of these surgeries and could no longer work. As a result of his hip pain and limited mobility, Alan developed depression and insomnia. Alan underwent revision surgery to remove both Conserve Plus implants in 2012 and 2013.

5. The Plaintiff Tony had a total hip arthroplasty on January 20, 2006 and had a Conserve Hip System, specifically a Conserve Plus implanted in his left hip. The pain in his left hip

worsened after the surgery. He could no longer work in his full-time position as an aircraft engineer. On February 2, 2007, Tony had a total hip arthroplasty on his right hip and received a different brand of implant that did not cause him discomfort. He continued to experience pain in his left hip, and eventually received a total hip arthroplasty on his left hip on October 25, 2007 to remove the Conserve Plus. Unfortunately, the revision did not alleviate his pain. Tony developed alcoholism as he turned to alcohol as a last resort form of pain management. He has also developed depression and suicidal ideation. He continues to struggle with his constant hip pain as well as his mental health.

6. The Plaintiff Pierre had hip resurfacing surgery on March 20, 2104. He had a Conserve Hip System, specifically a Conserve A-Class, implanted into his right hip. Shortly thereafter, Pierre developed an infection. After two years, Pierre developed a painful streptococcus infection at the site of his right hip implant. He also developed a pseudotumor on his right hip. His pain and discomfort continued until he finally underwent right hip revision surgery on October 3, 2016.

7. Alan's wife, Lorrie, has suffered emotional anguish as a result of Alan's extreme pain and suffering. As Alan has been unable to work due to his pain, Lorrie continues to suffer financially, despite working to support their family.

8. The Plaintiffs allege that the Conserve Hip System is inherently defective and that the Defendants knew or ought to have known about these defects, yet they failed to disclose the defects to the Class Members and the regulatory authorities, including the Food and Drug Administration ("FDA") and Health Canada, in a timely manner. This lack of disclosure caused

or contributed to injures suffered by Alan, Tony, Pierre and other Class Members as described *infra*.

The Parties

9. Alan is 51 years old and currently resides in Peterborough, Ontario. He has two children: Reid who is 14 years old, and Isabella who is 12 years old.

10. Lorrie is 47 years old. She is Alan's wife. She lives in Peterborough, Ontario with Alan.

11. Tony is 59 years old and lives in Enfield, Nova Scotia. He has one son, Jonathan, who is 31 years old, and three daughters, Alexandra, Madison, and Mackenzie, aged 29, 27 and 24 years old, respectively,

12. Pierre is 58 years old. He currently resides in Val-David, Quebec. He has three children: Marianne who is 36 years old, Francois Michel who is 28 years old and Marco who is 26 years old.

13. The Defendant, Wright Medical Group, Inc., is a Delaware Corporation with its principal place of business at 5677 Airline Road, Arlington, Tennessee. At all material times, Wright Medical Group, Inc. was a publicly traded holding company with wholly owned subsidiaries, that it controlled, and which designed, manufactured, marketed, supplied and sold the Conserve Hip System.

14. The Defendant, Wright Medical Technology, Inc., is a Delaware Corporation with its principal place of business at 5677 Airline Road, Arlington, Tennessee. At all material times, Wright Medical Technology Group, Inc. was the wholly owned subsidiary of the Defendant,

Wright Medical Group, Inc. and designed, manufactured, marketed, supplied and sold the Conserve Hip System.

15. The Defendant, Wright Medical Technology Canada Ltd., is a Canadian Limited company organized and existing under the laws of the Province of Ontario, with its principal place of business located at 6581 Kitimat Road, Unit 8 in Mississauga, Ontario. Wright Medical Technology Canada Ltd. is a wholly owned subsidiary of Wright Medical Group, Inc. and is in the business of marketing, importing and distributing into Canada medical devices, including the Conserve Hip System, designed and manufactured by related Wright Medical corporations, including Wright Medical Group, Inc. and Wright Medical Technology, Inc. Wright Medical marketed, imported and distributed the Conserve Hip System in Canada until MicroPort Scientific Corporation and MicroPort Medical B.V. purchased Wright Medical's OrthoRecon business, which manufactured the Conserve Hip System, on June 19, 2013.

16. MicroPort Scientific Corporation ("MicroPort Scientific") is a publicly traded company. It is traded on the Hong Kong stock exchange and has headquarters in Shanghai, China. MicroPort Scientific develops, manufactures, and sells interventional medical devices.

17. MicroPort Medical B.V. ("MicroPort Medical") is a privately held corporation based in Tiel, the Netherlands. It is in the business of manufacturing and distributing orthopaedic products, including the Conserve Hip System, through its wholly owned subsidiary, MicroPort Orthopedics Inc. MicroPort Medical is a wholly owned subsidiary of MicroPort Scientific (collectively, the "MicroPort Defendants" or "MicroPort").

18. On June 19, 2013, Wright Medical Group, Inc. entered into an agreement with MicroPort Scientific to sell its OrthoRecon business, which manufactured orthopaedic implants including

the Conserve Hip System, to MicroPort Scientific Corporation and MicroPort Medical B.V. MicroPort Scientific Corporation and MicroPort Medical B.V. subsequently transferred the business to MicroPort Orthopedics Inc, which continued to operate and manufacture and market the Conserve Hip System under the control of MicroPort Scientific Corporation and MicroPort Medical B.V., which had, at all times, knowledge of the defects associated with the Conserve Hip System and continued to fail to warn Canadian consumers of the increased risk of failure, physical injury, including tissue damage, and metallosis associated with their metal-on-metal devices. As a result, the MicroPort Defendants are also liable for claims arising from defects in the Conserve Hip System after this date. The precise role of each of the MicroPort Defendants as well as that of their subsidiaries and affiliates in manufacturing, testing, and marketing the Conserve Hip System is within the sole knowledge of the MicroPort Defendants.

19. The Defendants, Wright Medical Group, Inc., Wright Medical Technology, Inc., Wright Medical Technology Canada Ltd. (hereinafter collectively "Wright Medical" and/or the "Wright Defendants") each participated in one of more of the following: designing, developing, manufacturing, marketing, supplying, exporting, importing, and selling the Conserve Hip System. At all relevant times, each of the Wright Defendants acted on behalf of each other, and Wright Medical Group, Inc. exercised control over its subsidiaries and corporate divisions. As such, each Wright Defendant is individually, as well as jointly and severally, liable to the Plaintiffs and other Class Members for their injuries, losses and damages.

20. The MicroPort Defendants each participated in one or more of the following: manufacturing, licensing, marketing, supplying, exporting, importing, and selling the Conserve Hip System. At all relevant times, each of the MicroPort Defendants acted on behalf of each other, and MicroPort Scientific exercised control over its subsidiaries and corporate divisions,

including MicroPort Orthopedics Inc, and is liable for their actions As such, each MicroPort Defendant is individually, as well as jointly and severally, liable to the Plaintiffs and other Class Members for their injuries, losses and damages.

21. The Defendants each had a role in monitoring and reporting adverse events related to the Conserve Hip System, and had a role in the decision and response process, if any, to those adverse events.

22. In the alternative, particulars of the relationship between Wright Medical Group, Inc. and its co-defendants, as well as the role of each in the design, development, manufacture, marketing, supply, export, import, and sale of the Conserve Hip System, are solely within the knowledge of the defendants.

The Classes

23. Alan, Tony and Pierre bring this action on their own behalf and on behalf of the Class defined as follows:

> "All persons resident in Canada who were implanted with a Conserve Hip System (the "Class" and/or "Class Members")."

24. Lorrie brings this action on her own behalf and on behalf of the members of the Family Class defined as follows:

> "All persons who on account of a personal relationship to a Class Member are entitled to assert a derivative claim for damages pursuant to section 61(1) of the *Family Law Act*, R.S.O. 1990, c. F.3, as amended, and comparable provincial and territorial legislation. ("Family Class" and/or "Family Class Members")."

The Plaintiffs' Circumstances

a) **The Plaintiff Alan Chamberlain**

25. On March 8, 2010, Alan underwent surgery and had the Conserve Hip System, specifically the Conserve Plus, implanted in his right hip. Within three months of the surgery, Alan began to experience more pain in his hips than he had felt before the surgery. He could no longer walk long distances, run, skate, or ride a bike. Sitting for long periods of time was challenging for him.

26. On January 27, 2011, Alan received a hip resurfacing surgery on his right hip, and was implanted with a Conserve Plus as well.

27. After this surgery, Alan returned to his full-time job as a Personal Support Worker (PSW) for approximately one and a half months; however, his left hip pain flared. He could not stand for long periods of time, walk down the hall at his workplace, go up and down stairs, or do any heavy lifting. The pain medications he was taking made him vomit often. He could no longer do the physically demanding work of a PSW and had to stop working in the summer of 2011.

28. With Alan unable to work, his wife Lorrie had to support the family on her own, working full-time as a PSW. Alan could not even properly care for the couple's one year old daughter, Isabella, due to his condition. Alan's pain and his limited mobility and inability to care for his daughter led him to develop depression.

29. On August 22, 2012 Alan underwent a revision surgery on his left hip to have the Conserve Plus removed. He had a second revision surgery on January 30, 2013 to have the

Conserve Plus removed from his right hip. Despite these revision surgeries, Alan continues to experience constant pain in his hips.

b) The Plaintiff Tony Kinney

30. Tony underwent a total hip arthroplasty on January 20, 2006 to address his osteoarthritis and chronic hip pain. He received the Conserve Hip System, specifically the Conserve Plus.

31. Shortly after the surgery, Tony began to experience serious pain in his left hip and pelvis, which would keep him up at night. He also experienced pain in both his legs. Tony was taking pain medication but it was not providing him with significant relief. Tony could no longer work in his job as an aircraft engineer due to his severe hip pain after his surgery and the side effects of his pain medication.

32. Desperate for some relief, Tony elected to have a right hip replacement in 2006. On February 2, 2007, Tony had a total hip arthroplasty in his right hip. His right hip implant was not a Conserve Plus.

33. Tony continued to experience pain in his left hip. He turned to drinking alcohol to relieve his pain, and he developed alcoholism. Tony received a total hip arthroplasty on October 25, 2007 to remove the Conserve Plus implant. The revision did not alleviate his pain.

34. Due to complications from the Conserve Plus, Tony has been unable to return to work since 2007. Tony was receiving long-term disability benefits, but his family could barely survive on his disability income. In 2016, Tony was forced to sell his home and eventually ended up going through bankruptcy. His marriage ended during this time. Tony developed depression and suicidal ideation and attempted to commit suicide several times.

35. Today, Tony is housebound and experiences constant pain. While he no longer drinks alcohol, he is still struggling with both his physical pain and mental distress caused by his experience with Conserve Plus.

c) The Plaintiff Pierre Marchand

36. Pierre served in the Canadian Army in the infantry division for 34 years. In late 2013, Pierre was diagnosed with moderate to severe arthritis in his right hip. At 50 years of age, Pierre underwent right hip resurfacing on March 20, 2014 to address his moderate to advanced arthritis in his right hip.

37. Pierre received the Conserve Hip System, specifically a Conserve A-Class Femoral Component. Several weeks after his surgery, Pierre developed redness and swelling and an abscess on his right hip. He was diagnosed with a painful infection, which was only controlled after weeks of antibiotic treatment.

38. Two years later, on April 19, 2016, Pierre was diagnosed with a sepsis infection at the site of his implant. He also was diagnosed with a pseudotumor in his right hip.

39. In October 2016, Pierre underwent a hip revision surgery to remove his Conserve A-Class device. He was implanted with a different brand of hip implant. Pierre has had no major issues with his right hip since.

d) The Plaintiff Lorrie Chamberlain

40. Lorrie is Alan's spouse. Lorrie became Alan's primary caregiver after he lost his mobility due to complications from the Conserve Hip System, and assisted him daily with basic tasks.

41. As Alan could no longer work or help with household chores due to his extreme pain and his limited mobility, Lorrie had to support the family on her income alone. She worked full time, taking care of Alan as well as their young daughter Isabella, and completing all the household tasks.

42. With only one income, Lorrie and Alan struggled to make ends meet. They were forced to cash in their RRSPs, and go into debt to pay their expenses. This was stressful for both of them and put strain on their relationship. Lorrie and Alan have never regained financial stability.

43. Lorrie also suffered a significant loss of care and companionship as a result of Alan's pain and immobility caused by the Conserve Hip System. Lorrie, Alan and their daughter Isabella could not engage in physical activity as a family due to Alan's hip pain.

The Facts

44. Under the *Food and Drugs Act*, R.S.C. 1985, F-27, the Conserve Hip System is a Class III medical device. It may only be sold in Canada with the approval of Health Canada.

45. The Conserve Hip System is a "metal on metal" prosthesis system used in hip resurfacing surgery. In this surgery, the damaged head of the patient's femur is reshaped and "capped" or replaced with a metal prosthesis, and a corresponding prosthesis cup is fitted into the damaged hip acetabulum. These metal on metal hip prosthesis systems were widely marketed to physicians and patients as providing greater range of motion and greater durability than traditional hip prosthesis components, and were promoted by the Defendants as preferable for use in young, active individuals.

46. The acetabular component or metal "cup" of the Conserve Hip System is shallow and thin, and of such a design that it leads to excessive friction and wear of the metal articulating surfaces of the cup and femoral head.

47. The head and neck components of the Conserve Hip System were designed in such a way as to make them more susceptible to excessive friction and wear of the metal articulating surfaces, creating and releasing metallic ions and debris into the user's body.

48. The exterior surface of the cup of the Conserve Hip System does not adequately promote boney ingrowth to permanently affix the cup to the pelvis.

49. The surgical skill required for the implantation of the Conserve Hip System, so as to minimize the potential for excessive metal wear and maximize the potential for a successful implant, requires a degree of surgical precision beyond the generally accepted standard of care in the field of orthopaedic surgery.

50. The Conserve Hip System was marketed and promoted by the Defendants and their trained representatives for uses, longevity, and durability that exceeded its design, capabilities, and limitations known to the Defendants. The Defendants marketed the Conserve Hip System for use in women when they knew or ought to have known that use in women resulted in even greater risk of complications and revision.

51. At all material times, the Defendants knew that the Conserve Hip System was prone to failing due to loosening and metallosis, among other causes, and was therefore being revised at a rate higher than other comparable artificial hip systems in the market. In its Eighth Annual Report released in 2011, the National Joint Registry for England and Wales identified the

Conserve Plus Total Resurfacing Hip System as having a revision rate of 1.91 percent one year after implantation, 4.29 percent at three years, and 7.99 percent at five years. By contract, all resurfacing implants required revision at rates of 1.14 percent at one year, 2.6 percent at three years, and 4.36 percent at five years. Other forms of non-metal on metal hip placement systems demonstrated even lower revision rates. In its Ninth Annual Report released in 2012, the National Joint Registry for England and Wales identified the Conserve Plus as having demonstrated an increase in revision rates, with a rate of 2 percent after one year, 5.16 percent after three years, and 8.52 percent after five years.

52. At all material times, the Defendants failed to warn patients, surgeons, customers or its field representatives that the Conserve Hip System was known to be failing or revised at higher than expected rates, and at rates higher than other comparable artificial hip systems in the market that did not employ a metal on metal design for their articulating surfaces. They also did not warn patients, surgeons, customers, or field representatives that the Conserve Hip System was at additional risk of failure when implanted in women.

53. Despite their knowledge that the Conserve Hip System was failing or revised at higher than expected rates, and at rates higher than other comparable artificial hip systems in the market that did not employ a metal on metal design for their articulating surfaces, the Defendants continued to market, manufacture, distribute, and sell the Conserve Hip System in Canada, thus exposing the Plaintiffs and the Class Members to the risk of early revisions, bone and tissue damage, metallosis, a diminished quality of life, and psychological pain and suffering.

The Defendants' Negligence

54. The Conserve Hip System was designed, developed, tested, manufactured, licensed, assembled, distributed, imported and/or exported, marketed, and/or sold by the Defendants. At all material times, the Defendants owed a duty of care to the Plaintiffs and the other Class Members to provide a safely designed and manufactured product, and to warn health care professionals, regulators, the Plaintiffs and the other Class Members of the defective nature of the Conserve Hip System. The Defendants breached the standard of care expected in the circumstances.

55. The Defendants were negligent in the design, development, testing, manufacturing, licensing, assembly, distribution, importing and/or exporting, marketing and sale of the Conserve Hip System.Particulars of some, but not all, of the Defendants' acts of negligence are as follows:

(i) they knew or should have known that the Conserve Hip System was susceptible to unreasonable and higher than average implant failure rates;

(ii) they knew that the Conserve Hip System was dangerously defective and failed to warn the public, health care providers and the regulatory authorities in a timely manner;

(iii) they failed to adequately test the safety and efficacy of the Conserve Hip System before marketing and distributing it;

(iv) they failed to adequately design, manufacture and/or test the Conserve Hip System ensure that it was safe and free from defects prior to selling or distributing it;

(v) they failed to assemble and manufacture the Conserve Hip System in such a manner that it would operate safely and effectively without exposing the Defendants' consumers to injury or loss during and after implantation;

(vi) they knew or ought to have known that the Conserve Hip System was defective and that it would not properly perform the functions or purposes for which it was intended;

(vii) they failed to take any steps to fix the defects in the Conserve Hip System after they knew of the defects and the injuries and risks associated with its use;

(viii) they failed to warn the Plaintiffs and Class Members, health care providers and regulators that the Conserve Hip System was defective;

(ix) they failed to provide clear instructions to physicians and patients, including precautions to be taken, so as to avoid injury or damages from the Conserve Hip System;

(x) they used defective components to manufacture the Conserve Hip System;

(xi) they concealed the fact that the Conserve Hip System was defective from the public, health care providers and the regulatory authorities, including the FDA and Health Canada;

(xii) they concealed adverse information regarding the testing and safety of the Conserve Hip System from the public, health care providers and regulatory authorities, including the FDA and Health Canada;

(xiii) they failed to monitor and follow up on reports of adverse reactions to the Conserve Hip System;

(xiv) they incorrectly blamed failures of the Conserve Hip System on surgical error instead of following up on and investigating documented cases of failure;

(xv) they failed to properly train their employees responsible for the design, testing, assembly and manufacturing of the Conserve Hip System;

(xvi) they failed to ensure that their employees complied with the appropriate quality system standards applicable to the manufacturing process;

(xvii) they failed to properly supervise their employees and subsidiaries; and

(xviii) they failed to issue a safety notice or to recall the Conserve Hip System in a timely manner.

56. At all times the Defendants knew, and had reason to know, that the Conserve Hip System was not safe for the patients in whom it was implanted, because the Conserve Hip System failed to operate in a safe and continuous manner, causing serious medical problems, pain and, in many patients, the need for revision surgery.

57. The Defendants knew and had reason to know of the defects in the Conserve Hip System, but concealed this information and did not warn the Plaintiffs, the Class Members, physicians, or regulators. This prevented the Plaintiffs, the Class Members, their physicians, and the medical community from making informed choices about the selection of the Conserve Plus Total Resurfacing Hip System for implantation.

58. In committing the foregoing acts, the Defendants breached the *Food and Drugs Act,* R.S. 1985, c. F-27 and the *Medical Devices Regulations*, SOR/98-282. Particulars of some, but not all, of the Defendants' violations of the *Medical Devices Regulations* are:

a) failure to keep objective evidence to establish that the Conserve Hip System met the safety requirements (s. 9(2));

b) failure to eliminate or reduce the risk that the Conserve Hip System would loosen or fail and failure to warn against this risk (section 10);

c) failure to assess the risks of the Conserve Hip System against its benefits, and selling the Conserve Hip System despite its risks outweighing its benefits (section 11);

d) failure to ensure that the product was effective for the uses for which it was represented (section 12);

e) failure to instigate an effective and timely investigation into complaints of the Conserve Hip System and to carry out an effective and timely recall of the device (section 58); and

f) failure to report incidents of failure of the device inside or outside of Canada (sections 59-61.1).

Breach of Warranty

59. The Defendants warranted to Alan, Tony, Pierre and other Class Members that the Conserve Hip System was of merchantable quality and fit for use. The Defendants breached the

warranty to the Plaintiffs and other Class Members by manufacturing, testing, marketing, distributing and selling the Conserve Hip System, which was inherently dangerous to users.

60. In allowing the implantation of the Conserve Hip System Alan, Tony, Pierre and other Class Members and their physicians relied on the skill, judgment, representation and warranties of the Defendants. These warranties and representations were false in that the Conserve Hip System was not safe and was unfit for the uses for which it was intended.

61. The defective condition of the Conserve Hip System existed at the time it left the Defendants' control.

Damages

62. As a result of the negligence of the Defendants, the Plaintiffs and other Class Members have suffered damages and losses, including, but not limited to:

(a) severe physical pain and suffering as a result of the defects in the Conserve Hip System;

(b) enduring painful medical procedures to remove and replace the Conserve Hip System;

(c) emotional distress, including mental distress, anger, depression and anxiety;

(d) the risk of serious injuries;

(e) costs associated with replacing the Conserve Hip System and related medical care expenses;

(f) out-of-pocket expenses incurred by the Class Members;

(g) loss of income; and

(h) such further and other damages the particulars of which will be provided prior to trial.

63. As a result of the Defendants' negligence, Lorrie and other Family Class Members have suffered damages, including:

a) Actual expenses reasonably incurred for the benefit of the Plaintiffs and other Class Members;

b) Travelling expenses incurred while visiting Alan and other Class Members during treatment and recovery;

c) Loss of income and the value of services provided by and for Alan and other Class Members; and

d) Loss of support, guidance, care and companionship that they might reasonably have expected to receive from Alan and other Class Members.

Punitive Damages

64. The Plaintiffs plead that the Defendants' conduct in the design, development, testing, manufacture, licensing, assembly, distribution, exporting and/or importing, marketing, and sale of the Conserve Hip System, the failure to recall the Conserve Hip System, and the facts pleaded above, were high-handed, outrageous, reckless, wanton, entirely without care, deliberate, callous, and in intentional disregard of the Plaintiffs' and Class Members' rights and safety, indifferent to

the consequences, and motivated by economic considerations such as maintaining revenue and market share. The Defendants deliberately continued to manufacture, market, distribute and sell the Conserve Hip System, and continued to represent to Canadians that this product was safe for its intended use, despite clear medical evidence in the early 2000s that metal on metal bearing surfaces were associated with an unacceptably high rate of early failure and had caused serious, and in many instances, permanent harm to those implanted with these devices. The Defendants' reckless disregard for public safety is deserving of condemnation by means of an award of punitive damages

Provincial Health Insurers

65. The provincial and territorial health insurers in Canada have incurred various expenses with respect to the medical treatment of Alan, Tony, Pierre and other Class Members as a result of the Defendants' negligence. As a result, they have suffered and will continue to suffer damages for which they are entitled to be compensated by virtue of their subrogated and direct rights of action in respect of all past and future insured services. This action is maintained on behalf of all such provincial and territorial health insurers.

Legislation

66. The Plaintiffs plead and rely upon, *inter alia,* the following statutes and the regulations made thereunder (all as amended):

(i) *Alberta Health Care Insurance Act, R.S.A. 200, c. A-20;*

(ii) *Class Proceedings Act, 1992, S.O. 1992, c. 6;*

(iii) *Courts of Justice Act*, R.S.O. 1990, c. C.43;

(iv) *Department of Health Act*, R.S.S. 1978, c. D-17;

(v) *Family Law Act*, R.S.O. 1990, c. F.3;

(vi) *Fatal Accident Act*, R.S.N.L. 1990, c. F-6;

(vii) *Fatal Accidents Act*, C.C.S.M. c. F50;

(viii) *Fatal Accidents Act*, R.S.A. 2000, c. F-8;

(ix) *Fatal Accidents Act*, R.S.N.B. 1973, c. F-7;

(x) *Fatal Accidents Act*, R.S.N.W.T. 1988, c. F-3;

(xi) *Fatal Accidents Act*, R.S.P.E.I. 1988 c. F-5;

(xii) *Fatal Accidents Act*, R.S.S. 1978, c. F-11;

(xiii) *Fatal Accidents Act*, R.S.Y. 2002, c. 86;

(xiv) *Fatal Injuries Act*, R.S.N.S. 1989, c. 163;

(xv) *Food and Drugs Act*, R.S.C. 1985, c. F-27 and applicable regulations, including *Medical Device Regulations*, SOR/98-282;

(xvi) *Health Insurance Act,* R.S.O. 1990, c. 11.6;

(xvii) *Health Services and Insurance Act*, R.S.N.S. 1989, c. 197;

(xviii) *Health Services Insurance Act*, C.C.S.M., C.1135;

(xix) *Hospital and Diagnostic Services Insurance Act*, R.S.P.E.I. 1988, c. H-8;

(xx) *Hospital Insurance Agreement Act*, R.S.N.I. 1990, c.11-7;

(xxi) *Hospital Insurance and Health and Social Services Administration Act*, R.S.N.W.T. 1988, c. T-3;

(xxii) *Hospital Insurance Services Act*, R.SY. 2002, c. 112;

(xxiii) *Hospital Services Act,* R.S.N.B. 1973, c. 11-9;

(xxiv) *Hospitals Act*, R.S.A. 2000, c. 11-12;

(xxv) *Negligence Act*, R.S.O. 1990, c. N.1;

(xxvi) the *Trustee Act*, C.C.S.M. c. T160;

(xxvii) *Trustee Act*, R.S.N.W.T. 1988, c. T-8; and

(xxviii)*Trustee Act,* R.S.O. 1990, c. T.23.

Real and Substantial Connection with Ontario

67. The Plaintiffs plead that this action has a real and substantial connection with Ontario because, among other things:

a) the Defendant, Wright Medical Technology Canada Ltd., has a registered place of business in Ontario;

b) the Defendants carry on business in Ontario;

c) the Defendants distribute and sell their products in Ontario and derive substantial revenue from such sales;

d) the damages of the Plaintiffs and those of the other Class Members resident in Ontario were sustained in Ontario;

e) the Defendant, Wright Medical Technology, Inc., made applications to Health Canada in Ottawa, Ontario for permission to market the Conserve Hip System;

f) the MicroPort Defendants (through their wholly owned and controlled subsidiary MicroPort Orthopedics Inc.) currently own the medical device license from Health Canada to market the Conserve Hip System in Canada, including Ontario, and they marketed and distributed their products, including the Conserve Hip System in Ontario; and

g) the Defendants advertised their products, including the Conserve Hip System in Ontario.

Service

68. This originating process may be served without court order outside Ontario because the claim is:

a) in respect of a tort committed in Ontario (rule 17.02(g));

b) in respect of damages sustained in Ontario arising from a tort or breach of contract however committed (rule 17.02(h));

c) against a person outside Ontario who is a necessary and proper party to this proceeding properly brought against another person served in Ontario (rule 17.02(o)); and,

d) against a person carrying on business in Ontario (rule 17.02(p)).

69. The Plaintiffs request that this matter be tried in the City of Toronto.

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ONTARIO
SUPERIOR COURT OF JUSTICE

PROCEEDING COMMENCED IN
TORONTO

FRESH AS AMENDED STATEMENT OF CLAIM

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