Form 4.02A

2011

Hfx. No. 355381

SUPREME COURT OF NOVA SCOTIA

BETWEEN:

RODRICK DESBOROUGH

PLAINTIFF

- and -

WRIGHT MEDICAL TECHNOLOGY CANADA LTD, **WRIGHT MEDICAL TECHNOLOGY, INC.**, and **WRIGHT MEDICAL GROUP, INC.**

DEFENDANTS

Proceeding under the *Class Proceedings Act*, S.N.S. 2007, c. 28

Notice of Action –Third Fresh as Amended May 1 , 2019

TO: **Wright Medical Technology Canada Ltd**
6581 Kitimat Road Unit 8
Mississauga Ontario L5N 3T5

TO: **Wright Medical Technology, Inc.**
2711 Centreville Road, Suite 400
Wilmington New Castle DE 19808

TO: **Wright Medical Group, Inc.**
2711 Centreville Road, Suite 400
Wilmington New Castle DE 19808

Action has been started against you

The Plaintiff takes action against you.

The Plaintiff started the action by filing this notice with the court on the date certified by the Prothonotary. The Plaintiff claims the relief described in the attached second amended statement of claim. The claim is based on the grounds stated in the second amended statement of claim.

Deadline for defending the action

To defend the action, you or your counsel must file a notice of defence with the court no more than the following number of days after the day this notice of action is delivered to you:

- 15 days if delivery is made in Nova Scotia
- 30 days if delivery is made elsewhere in Canada
- 45 days if delivery is made anywhere else.

Judgment against you if you do not defend

The court may grant an order for the relief claimed without further notice, unless you file the notice of defence before the deadline.

You may demand notice of steps in the action

If you do not have a defence to the claim or you do not choose to defend it you may, if you wish to have further notice, file a demand for notice.

If you file a demand for notice, the Plaintiff must notify you before obtaining an order for the relief claimed and, unless the court orders otherwise, you will be entitled to notice of each other step in the action.

Rule 57 - Action for Damages Under $100,000

Civil Procedure Rule 57 limits pre-trial and trial procedures in a defended action so it will be more economical. The Rule applies if the Plaintiff states the action is within the Rule. Otherwise, the Rule does not apply, except as a possible basis for costs against the Plaintiff.

This action is *not within* Rule 57.

Filing and delivering documents

Any documents you file with the court must be filed at the office of the Prothonotary, 1815 Upper Water Street, Halifax, Nova Scotia (telephone # 424-4900).

When you file a document you must immediately deliver a copy of it to each other party entitled to notice, unless the document is part of an *ex parte* motion, the parties agree delivery is not required, or a judge orders it is not required.

Contact information

The Plaintiff designates the following address:

Raymond F. Wagner, Q.C.
Wagners
1869 Upper Water Street
Suite PH301, Historic Properties
Halifax NS B3J 1S9
Documents delivered to this address are considered received by the Plaintiff on delivery.

Further contact information is available from the Prothonotary.

Proposed place of trial

The Plaintiff proposes that, if you defend this action, the trial will be held in Halifax, Nova Scotia.

Signature

Signed this 13th day of September, 2011.

Amended this 29th day of May, 2013.

Second Amended this 16th day of August, 2013.

Second Fresh Amended this 16th day of August, 2013.

Third Amended this 1ST day of May, 2019.

Third Fresh as Amended this 1ST day of May, 2019.

RAYMOND F. WAGNER, Q.C.
Solicitor for the Plaintiff

Prothonotary's certificate

I certify that this third fresh as amended notice of action, including the attached third fresh as amended statement of claim, was filed with the court on May 1, 2019.

~~Prothonotary~~
JENNA BENT
Deputy Prothonotary

FORM 4.02B

THIRD FRESH AS AMENDED STATEMENT OF CLAIM

Proceeding under *the Class Proceedings Act*, S.N.S 2007, c. 28

I. OVERVIEW

1. The Profemur Hip Implant System was developed in order to reconstruct human hip joints that are diseased due to conditions such as osteoarthritis, rheumatoid arthritis, avascular necrosis, and fracture.

2. The Profemur Hip Implant System was designed to replace all or some of the parts of diseased hip joints in order to alleviate symptoms of such health conditions.

3. The Profemur Hip Implant System is composed of a Profemur Modular Stem (i.e. a Profemur Z stem, Profemur Plasma Z stem, Profemur LX stem, Profemur Tapered stem, Profemur RAZ stem, Profemur TL stem, Profemur Xm stem, or Profemur Renaissance stem) with a Profemur neck and femoral head. This modularity purports to allow orthopaedic surgeons more options for modifying the implant's geometry and should yield better results than conventional hip replacement systems.

4. The Profemur Hip Implant System received licensing approval from Health Canada in February 2001.

5. The Profemur Hip Implant System was approved in the United States by the Food and Drug Administration ("FDA") through a controversial 510(K) pre-market approval process. In this process, the manufacturer had to demonstrate only that the Profemur Hip Implant System was substantially equivalent to an existing medical device to obtain approval.

6. The Defendants have aggressively marketed the Profemur Hip Implant System as having advantages over other hip replacement or resurfacing systems. The Defendants advertised the Profemur Hip Implant System as a suitable, safe, effective, minimally invasive hip replacement, and as a

"high performance" system.

7. The majority of total hip implant surgeries demonstrate an average longevity of ten to fifteen years before requiring a revision.

8. The Annual 2009 Report of the Australian Joint Registry advised that the Profemur Z Stem component of the Profemur Hip Implant System has an 11.2% failure rate at the three year interval.

9. For at least two years, the Defendants knew, contrary to their marketing campaigns, that a disproportionately high number of their Profemur Z Stems were failing and harming patients. The Defendants were aware of many complaints made to FDA and Health Canada regarding the failure of their Profemur Hip Implant Systems. The failure of these hip implants often requires complicated, expensive and painful revision surgery to correct.

10. The Defendants, however, consistently failed to disclose or warn Canadian patients of the significant risk of failure in the Profemur Hip Implant System. The Defendants knew or ought to have known of the significant risks associated with the use of Profemur Hip Implant System.

II. THE REPRESENTATIVE PLAINTIFF

11. The Plaintiff, Rodrick Desborough, resides at 180 Spinnaker Drive, Halifax, Nova Scotia.

12. The Plaintiff seeks to certify this action as a Class Proceeding and pleads the *Class Proceedings Act*, S.N.S. 2007, c. 28, as the basis for such certification. The Representative Plaintiff does not have any interest adverse to any of the members of the proposed class. The Plaintiff states that there is an identifiable class that would be fairly and adequately represented by the Plaintiff; that the Plaintiff's claim raises common issues; and that a class proceeding would be the preferable procedure for the resolution of such common issues.

13. The Plaintiff proposes to bring a class proceeding on behalf of himself and a class of all other Canadian residents who have been implanted with a

Profemur Hip Implant System at any time between February 2001 to the date of certification of this proceeding and who have suffered a fracture of the Profemur Hip Implant System (the "Class" or "Class Members"). The proposed class will be further defined in the motion for Certification.

III. DEFENDANTS

14. 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, Mississauga, Ontario L5N 3T5. Wright Medical Technology Canada Ltd. manufactures, markets and distributes the Profemur Hip Implant System in Canada.

15. Wright Medical Technology, Inc. is a corporation organized and existing under the laws of the state of Delaware with its principal place of business located at 5677 Airline Road, Arlington, Tennessee 38002, and its registered office located at 2711 Centreville Road, Suite 400 Wilmington New Castle DE 19808. Wright Medical Technology, Inc. designed, manufactures, markets and distributes the Profemur Hip Implant System throughout the United States.

16. Wright Medical Group, Inc. is a corporation organized and existing under the laws of the state of Delaware with its principal place of business located at 5677 Airline Road, Arlington, Tennessee 38002 and its registered office located at 2711 Centreville Road, Suite 400 Wilmington New Castle DE 19808. Wright Medical Group, Inc. is the parent company of both Wright Medical Technology Canada Ltd, and Wright Medical Technology, Inc.

17. Wright Medical Technology Canada Ltd, Wright Medical Technology, Inc., and Wright Medical Group, Inc. shall herein be referred to individually by name or jointly as "the Defendants."

18. At all material times, the Defendants carried on business jointly in and throughout Canada from Wright Medical Technology Canada Ltd.'s head

office in Mississauga. Collectively the Defendants researched, developed, tested, manufactured, marketed, distributed and sold the Profemur Hip Implant System as an appropriate, cost efficient, suitable, safe and effective medical product for use in hip replacement surgery throughout Canada.

IV. NATURE OF THE ACTION

19. The Defendants are U.S. and Canadian corporations involved in the design, manufacture, labelling, marketing, distribution and sale of the Profemur Hip Implant System.

20. The Profemur Hip Implant System was designed and manufactured improperly. These implants cause and have caused serious bodily injury and economic loss to the Plaintiff and the Class. The Defendants knew or ought to have known that these products were improperly designed and manufactured at the time they introduced the products into the marketplace. The Defendants never properly warned the Plaintiff or the Class about the risks associated with their products. The Defendants should not have sold improperly designed and manufactured products.

21. The Defendants' actions were unlawful and the Defendants knew or should have known that injury to the Plaintiff and the Class would result from their actions.

22. The risks associated with the Profemur Hip Implant System were within the Defendants' exclusive knowledge and control. The Plaintiff and the Class did not know and could not reasonably have been expected to know the extent of the risks. The injuries of the Plaintiff and the Class would not have occurred but for the negligence of the Defendants in failing to ensure that the Profemur Hip Implant System was safe for use or, in the alternative, for failing to provide an adequate warning of the risks associated with the Profemur Hip Implant System to the Plaintiff, to the Class and to their physicians.

23. The Defendants were aware of the defect in manufacture and design prior

to the annual 2009 Report of the Australian Joint Registry. Nevertheless, they continued to market, distribute, and sell Profemur Hip Implant Systems.

24. The Defendants' conduct was unlawful because they knowingly marketed and sold Profemur Hip Implant Systems and permitted the Profemur Hip Implant System to be implanted into members of the Class. Despite knowing, or having reason to know, that the Profemur Hip Implant System was defective, the Defendants concealed the risks from members of the Class, health care providers, the medical community, and regulatory authorities, including Health Canada and the FDA.

V. HARM TO THE PLAINTIFF

25. On or about April 30, 2007, Rodrick Desborough underwent a left total hip arthroplasty and had a Profemur Hip Implant System implanted.

26. On or about April 2, 2010, Rodrick Desborough suffered a fracture of his Profemur Hip Implant System.

27. On or about April 5, 2010, Rodrick Desborough underwent a revision surgery as a result of the fracture of his Profemur Hip Implant System.

28. He continues to endure chronic discomfort and pain as a result of the failure of his Profemur Hip Implant System and the subsequent revision surgery that failure necessitated.

VI. CAUSES OF ACTION

(a) Negligent design, development and testing:

29. The Defendants owed the Plaintiff and Class Members a duty of care as follows:

    (a) to ensure that the Profemur Hip Implant System was thoroughly and appropriately tested so as to determine if there were any potentially adverse side effects associated with the product;

(b) to ensure that the Profemur Hip Implant System was fit for its intended or reasonably foreseeable use;

(c) to design, develop and test the Profemur Hip Implant System using methods and processes that conform to industry standards and regulations; and

(d) to conduct appropriate follow-up studies on the efficacy and safety of the Profemur Hip Implant System.

30. The Defendants were negligent in the design, development and testing of the Profemur Hip Implant System. Such negligence includes, but is not limited to the following, that the Defendants jointly and severally:

(a) failed to thoroughly and appropriately test the Profemur Hip Implant System to determine the magnitude of the risks associated with its use, including but not limited to the risk of fracture;

(b) failed to conduct adequately powered studies and testing to determine the potential induction of micro cracks in the Profemur Hip Implant System:

(c) designed and developed the Profemur Hip Implant System in a manner that caused early fatigue initiation when they knew, or should have known, that this significantly increases the premature catastrophic failures;

(d) designed and developed the Profemur Hip Implant System in a manner that caused an increased propensity for fracture of the prosthesis neck, when they knew or ought to have known that the design carried with it this increased risk;

(e) conducted inadequate or no follow-up studies on the efficacy and safety of the Profemur Hip Implant System;

(f) failed to conform to industry standards, practices and regulations in the design, development and testing of the Profemur Hip Implant System;

(g) failed to conform with applicable disclosure and reporting obligations;

(h) failed to monitor the post-market effects of the Profemur Hip Implant System;

(i) failed to conduct appropriate follow-up studies when the risks of the Profemur Hip Implant System became known to them;

(j) disregarded reports of symptoms of adverse events among patients who participated in clinical trials of the Profemur Hip Implant System;

(k) failed to instruct their employees to properly monitor and record complaints of adverse health effects of the Profemur Hip Implant System;

(l) hired incompetent personnel and failed to adequately supervise the personnel conducting the design, development and testing of the Profemur Hip Implant System; and,

(m) failed to take reasonable steps to ensure that the Profemur Hip Implant System was fit for its intended or reasonably foreseeable use.

31. There existed alternative designs which were safer and economically feasible to manufacture.

32. The negligence of the Defendants in the design, development and testing of the Profemur Hip Implant System created a substantial likelihood of harm for patients who have been implanted with the Profemur Hip Implant System. The Plaintiff and Class Members have suffered harm and damages as a result of the Defendant's negligence.

(b) Negligent Manufacturing

33. The Defendants owed the Plaintiff and Class Members a duty of care as follows:

    (a) to conform to industry standards, practices and regulations in the manufacturing of the Profemur Hip Implant System;

    (b) to conduct adequate and routine inspections of the plants manufacturing the Profemur Hip Implant System; and

    (c) to have adequate and appropriate quality control methods in place at the plants manufacturing the Profemur Hip Implant System.

34. The Defendants were negligent in the manufacturing of the Profemur Hip Implant System. Such negligence includes, but is not limited to the following, that the Defendants jointly and severally:

    (a) failed to meet industry standards, practices and regulations in the manufacturing of the Profemur Hip Implant System;

    (b) failed to adequately and routinely inspect the plants manufacturing the Profemur Hip Implant System;

    (c) manufactured the Profemur Hip Implant System without having in place adequate quality control protocols, or in disregard of those protocols;

    (d) hired incompetent personnel and failed to adequately supervise the personnel manufacturing the Profemur Hip Implant System; and

    (e) continued to manufacture the Profemur Hip Implant System when they knew or ought to have known that this product caused or could cause serious health problems.

35. The Plaintiff and Class Members have suffered harm and damages as a result of the Defendants' negligence in the manufacturing of the Profemur Hip Implant System.

(c) Negligent distribution, marketing and sale

36. The Defendants owed the Plaintiff and Class Members a duty of care as follows:

    (a) to warn the Plaintiff and Class Members that the Profemur Hip Implant System carried a significant risk of adverse events and early revision;

    (b) to take reasonably necessary and appropriate steps to ensure that prescribing physicians were appraised and fully and regularly informed of all the health risks associated with the implantation of the Profemur Hip Implant System; and

    (c) to inform Health Canada and other regulating agencies fully, properly, and in a timely manner of the failure risks and complaints associated with the implantation of the Profemur Hip Implant System.

37. The Defendants were negligent in the distribution, marketing and sale of the Profemur Hip Implant System. Such negligence includes, but is not limited to the following, that the Defendants jointly and severally:

    (a) misinformed Health Canada by providing it with incomplete and inaccurate information concerning the Profemur Hip Implant System;

    (b) concealed or misled the Plaintiff, Class Members and their physicians concerning the risks associated with implantation of the Profemur Hip Implant System;

    (c) failed to provide the Plaintiff, Class Members and their physicians with appropriate warnings concerning the failure risks associated with the implantation of the Profemur Hip Implant System;

(d) failed to provide the Plaintiff, Class Members and their physicians with updates and current information on the risks and efficacy of the Profemur Hip Implant System as such information became available from time to time;

(e) failed to provide appropriate warnings of the adverse health risks and early failure rates associated with the use of the Profemur Hip Implant System on package labels or customer information pamphlets in Canada;

(f) failed to warn the Plaintiff and Class Members and their physicians and health regulators about the need for comprehensive regular medical monitoring necessary to assist in the early discovery of problems associated with the implantation of the Profemur Hip Implant System;

(g) after receiving actual and constructive notice of the failure risks associated with the Profemur Hip Implant System, failed to issue adequate warnings, recall the product in a timely manner, publicize the risks and otherwise act properly and in a timely manner to alert the public, including warning the Plaintiff and Class Members and their physicians and health regulators of the product's inherent risks;

(h) engaged in a system of improper and inadequate direction to their sales representatives and physicians respecting the correct usage of the Profemur Hip Implant System and the failure risks associated with the product;

(i) represented that the Profemur Hip Implant System was safe and fit for its intended purpose and of merchantable quality when they knew or ought to have known that these representations were false;

(j) misrepresented the state of research, opinion and medical literature pertaining to the purported benefits of the Profemur Hip Implant System and its associated failure risks;

(k) continued to manufacture, market and promote the selling and/or distribution of the Profemur Hip Implant System when they knew or ought to have known that this product caused or could cause serious problems; and.

(l) actively encouraged aggressive implanting of the Profemur Hip Implant System while neglecting to inform consumers, retailers, hospitals, and physicians of the increased failure risks associated with the Profemur Hip Implant System, when they knew or ought to have known about these increased risks;

(m) continued to manufacture, distribute and sell the Profemur Hip Implant System notwithstanding that:

i. the FDA and Health Canada had received numerous complaints involving patients with Profemur Hip Implant Systems; and

ii. the annual 2009 Report of the Australian Joint Registry shows that the Profemur Z Stem component of the Profemur Hip Implant System has an 11.2% failure rate at the three year interval;

38. The Plaintiff and Class Members have suffered harm and damages as a result of the Defendants' negligence in the distribution, marketing and sale of the Profemur Hip Implant System.

39. The Defendants' negligence in the design, development, testing, manufacture, distribution, marketing and sale of the Profemur Hip Implant System is in breach of the requirements of the *Medical Devices Regulations,* S.O.R./98-282

(d) Breach of the *Sale of Goods Act,* R.S., c. 408, s. 1

40. The Plaintiff pleads and relies upon the *Sale of Goods Act,* R.S. c. 408, s. 1. The Profemur Hip Implant System was purchased by the Plaintiff and Class Members pursuant to agreements within the meaning of the *Sale of Goods Act.* The Defendants represented the Profemur Hip Implant System as a suitable, safe, effective, minimally invasive hip replacement, and as a "high performance" system. The Defendants represented the Profemur Hip Implant System as having advantages over other hip replacement or resurfacing systems. These representations were in fact false, misleading or deceptive.

41. The Plaintiff pleads that the Profemur Hip Implant System was neither fit for its intended purpose nor of merchantable quality as a suitable, safe, effective, minimally invasive hip replacement and as a "high performance" system, or as having advantages over other hip replacement or resurfacing systems. In making contrary representations, the Defendants acted in breach of section 17 of the *Sale of Goods Act.*

VII. DAMAGES

42. As a result of the conduct of the Defendants as hereinbefore set out, the Plaintiff and Class Members have sustained serious personal injuries and damages.

43. As a result of the conduct of the Defendants, the Plaintiff and Class Members suffered and continue to suffer expenses and special damages of a nature and an amount to be particularized prior to trial.

44. Some of the expenses related to the medical treatment that the Plaintiff and Class Members have undergone, and will continue to undergo, have been borne by provincial health insurers. As a result of the negligence of the Defendants, the provincial health insurers have suffered and will continue to suffer damages.

(A) Manifest Harm and Injuries:

45. The past and ongoing use of the Profemur Hip Implant System has resulted in the Plaintiff's and Class Members' physical and mental health injuries pleaded above, and have also led to pain and suffering, loss of income, impairment of earning ability, loss of valuable services, future care costs, medical costs, loss of amenities and enjoyment of life, anxiety, nervous shock, mental distress, emotional upset, loss of consortium and out of pocket expenses.

46. The Plaintiff and Class Members assert a claim for each of the types of damages listed above.

VIII. AGGRAVATED, PUNITIVE AND EXEMPLARY DAMAGES

47. The Defendants manufactured, marketed, promoted and sold the Profemur Hip Implant System with full knowledge of the fact that they were adversely impacting the physical and psychological health of the Plaintiff and the Class Members. Knowledge of the risks associated with the use of the Profemur Hip Implant Systems was not released to the Plaintiff and Class Members. Despite having specific information that the Plaintiff and Class Members were at risk of serious problems associated with the use of the Profemur Hip Implant System, the Defendants continued or permitted the continuation of the manufacturing, marketing, promoting and selling of the Profemur Hip Implant System without reasonable controls.

48. These activities were carried out with reckless, callous and wanton disregard for the health, safety and pecuniary interests of the Plaintiff and other Class Members. The Defendants knowingly compromised the rights and interests of the Plaintiff and Class Members, solely for the purpose of monetary gain and profit. Furthermore, once the Defendants knew of the extraordinary dangers that the Profemur Hip Implant System posed to the Plaintiff and Class Members, the Defendants failed to advise the Plaintiff and Class of them in a timely fashion, fully or at all.

49. The Defendants' negligence was callous and arrogant and offends the ordinary community standards of moral and decent conduct. The actions and/or omissions of the Defendants involved such want of care as could only have resulted from actual conscious indifference to the rights, safety and welfare of the Plaintiff and Class Members.

50. Consequently, the Plaintiff and Class Members are entitled to aggravated damages, and an award of punitive and exemplary damages commensurate with the outrageous behaviour of the Defendants.

IX. GENERAL PROVISIONS

51. The Plaintiff and Class Members plead that, by virtue of the acts described herein, the Defendants are liable to them in damages. Each of the Defendants are vicariously liable for the acts and omissions of the others for the following reasons:

(a) each was the agent of the others;

(b) each Defendants' business was operated so that it was inextricably interwoven with the business of the others;

(c) each Defendant entered into a common advertising and business plan with the others to distribute and sell the Profemur Hip Implant System;

(d) each Defendant owed a duty to the others and to the Plaintiff and Class Member by virtue of the common business plan to distribute and sell the Profemur Hip Implant System; and

(e) each Defendant intended that the businesses be run as one global business organization.

52. The Plaintiff and Class Members state that the Defendants are liable, jointly and severally, for the injuries and damages suffered by the Plaintiff and other Class Members.

53. The Plaintiff and Class Members plead the doctrine of *respondeat superior* and state that the Defendants are vicariously liable to the Plaintiff and Class Members for the acts, omissions, deeds, misdeeds and liabilities of their contractors, sub-contractors, agents, servants, employees, assigns, appointees and partners.

54. The Plaintiff relies upon the statutes as set out in Schedule "A" hereto.

X. RELIEF SOUGHT

55. The Plaintiff repeats the foregoing paragraphs and seeks as relief the following:

(a) an Order certifying this proceeding as a national opt-out class proceeding and appointing the Plaintiff as Representative Plaintiff for the Class;

(b) general damages, including aggravated damages for personal injuries;

(c) special damages for medical expenses and other expenses related to the use of the Profemur Hip Implant System;

(d) aggravated, punitive and exemplary damages;

(e) The subrogated interests of the Provincial and Territorial health insurers includes the cost of all past and future insured services for the benefit of the Plaintiff and Class Members on account of defects in the Profemur Hip Implant System;

(f) interest;

(g) costs; and

(h) such further and other relief as this Honourable Court deems just.

PLACE OF TRIAL: Halifax, Nova Scotia

DATED at Halifax, Nova Scotia this 13th day of September, 2011.

AMENDED at Halifax, Nova Scotia this 29th day of May, 2013.

SECOND AMENDED at Halifax, Nova Scotia this 16th day of August, 2013.

SECOND FRESH AS AMENDED at Halifax, Nova Scotia this 16th day of August, 2013.

THIRD AMENDED at Halifax, Nova Scotia this day of May, 2019.

THIRD FRESH AS AMENDED at Halifax, Nova Scotia this day of May, 2019.

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