Electronically issued
Délivré par voie électronique : 14-Jan-2022
Toronto

Court File No.:

ONTARIO
SUPERIOR COURT OF JUSTICE

In the matter of a Claim under the
Class Proceedings Act, 1992, S.O. 1992, c. 6

B E T W E E N:

LYNNE KOSS

Plaintiff

- and -

ZIMMER BIOMET HOLDINGS, INC., BIOMET ORTHOPEDICS, LLC, ZIMMER BIOMET CANADA INC., and ZIMMER CAS

Defendants

STATEMENT OF CLAIM

TO THE DEFENDANT(S):

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 Plaintiff does not have a lawyer, serve it on the Plaintiff 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.

DATED:_____ **Issued by:**

_____

Court House
393 University Avenue, 10th Floor
Toronto, Ontario
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TO: **ZIMMER BIOMET HOLDINGS, INC.**
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AND TO: **BIOMET ORTHOPEDICS, LLC**
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AND TO: **ZIMMER BIOMET CANADA INC.**
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AND TO: **ZIMMER CAS**
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CLAIM

RELIEF SOUGHT

1. The Plaintiff claims on behalf of herself and on behalf of a class of individuals described in the class below:

   (a) an order certifying this action as a class proceeding and appointing the Plaintiff as Representative Plaintiff;

   (b) damages for each Class Member and the Plaintiff as follows:

      (i) general damages of $370,000 for pain and suffering and loss of amenities of life;

      (ii) damages for past and future loss of income in the amount of $2,000,000;

      (iii) damages for past and future cost of care in the amount of $3,000,000 per Class Member

      (iv) damages to indemnify the subrogated interests of the Ontario Health Insurance Plan and/or other private or provincial or territorial health insurers;

   (c) a declaration that the Defendants was jointly and/or severally negligent in the design, construction, manufacturing, inspection, testing and marketing of its ExploR Modular Radial Head System with ExploR Screw (trial number 418098, part number 11-210099) (the “Device”) used in patient elbow replacement operations, as well as its failure to warn patients

and/or surgeons and other healthcare providers of the inherent dangers and risks in using its Device and thereby causing loss and damage to the Plaintiff and other Class Members;

(d) aggravated, exemplary and/or punitive damages in the amount of $300,000,000 for these same claims to be divided pro rata amongst the Class Members;

(e) for Dependents of Class Members damages pursuant to the *Family Law Act,* RSO 1990, c F-3 ("*FLA*"), or equivalent in other provinces, for out-of-pocket expenses, loss of care guidance and companionship in the amount of $20,000,000;

(f) an Order requiring the Defendants to disclose for purposes of providing Opt Out Notice, the names, addresses and all contact information for each patient who had a device implanted in Canada;

(g) 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;

(h) Pre-judgment and post-judgment interest pursuant to the *Courts of Justice Act* ("*CJA")*;

(i) costs of this action on a substantial indemnity basis or in an amount that provides full indemnity plus, pursuant to s. 26(9) of the *Class Proceedings Act*, *1992, S.O. 1992, c. 6 ("CPA"),* the costs of notice and of administering the plan of distribution of the recovery in this action plus applicable taxes; and

(j) for approval of a 25% contingency fee agreement plus disbursements, HST.

THE PARTIES

2. The Plaintiff, Lynne Koss, is a resident of Thornhill, Ontario and underwent a Right Elbow Radial Head Replacement and Right Elbow Lateral Ligament Reconstruction ("Initial Surgery") on July 25, 2017, in which she had implanted the Defendants' ExploR Modular Radial Head System with ExploR Screw (trial number 418098, part number 11-210099) (the "Device").

3. The Defendant, Zimmer Biomet Holdings, Inc., is a corporation duly incorporated with its head office in Warsaw, Indiana in the United States. The Defendant Biomet Orthopedics, LLC ("Biomet Orthopedics") is a corporation duly incorporated with its head office in Warsaw, Indiana. Biomet Orthopedics is the legal manufacturer of the Device and is a subsidiary of the Defendant Company Zimmer Biomet Holdings, Inc. Zimmer Biomet Canada Inc. and Zimmer CAS are corporations duly incorporated and are subsidiaries or affiliates of the Defendant Company Zimmer Biomet Holdings, Inc. All of the Defendant companies work together and carry-on business of supplying medical devices including the ExploR Modular Radial Head System with ExploR Screw (trial number 418098, part number 11-210099) (the "Device"). All companies marketed distributed and profited by sales in Canada of the Device to Canadian patients.

THE CLASS

4. The Plaintiff brings this claim on her own behalf and on behalf of all other individuals who were surgical recipients of the Defendant's ExploR Modular Radial Head System with ExploR Screw (trial number 418098, part number 11-210099) which prematurely failed or is in the process of failing or has the Device implanted. In the alternative, individuals who were surgical recipients of the Device in which the proposed representative Plaintiff had implanted; and those individuals who are entitled, by virtue of their relationship to a member of the Class, to assert claims pursuant to the *Family Law Act* and equivalent legislation from other Canadian jurisdictions ("the Family Class").

FACTS

5. The corporate Defendants designed, manufactured and distributed the ExploR Modular Radial Head System with ExploR Screw (trial number 418098, part number 11-210099) (the "Device") which was advertised as being designed to "improve elbow function by restoring the stability and length of the radial head" and to offer an efficient, practical solution for treating patients and/or recipients with degenerative or post-traumatic conditions of the proximal radial head/neck.

6. The Device uses a modular design, which allows the head to be replaced without removing the implanted stem and reproduces the natural articulation of radio-capitellar and radio-ulnar joints. During partial elbow replacement surgeries using the Explor Modular Radial Head System with ExploR Screw (trial number

418098, part number 11-210099), surgeons implant the stem into the bone on one side of the joint and load the head from the side, which is secured with a setscrew to the stem.

7. The Device is comprised of an ExploR Modular Radial Head, an ExploR Modular Radial Stem, and an ExploR Screw. Although the ExploR Modular Radial Head and the ExploR Modular Radial Stem come in a variety of size, there is only one size ExploR Screw that is used in all Devices.

8. The Device was improperly designed, manufactured and tested resulting in the screw loosening and/or backing out into the elbow, ultimately resulting in device failure. There have been multiple reports concerning the screw loosening and/or backing out into the elbow.

9. The design of the ExploR Screw (trial number 418098, part number 11-210099) provided no warning about tightness and/or torque limiter for surgeons to follow. The class members say that as a result of negligent design, testing, and manufacturing, the Defendants are individually, severally and/or jointly responsible at law.

10. The Plaintiff on behalf of the Class says that all recipients in Canada will eventually require revision surgery to replace the defective Device.

11. The Plaintiff says that the Device prematurely fails as a result of the negligent design and procedures developed by the Defendants, which results in device failure, infection and/or complications, and subsequent revision surgeries, including total elbow replacements. The Plaintiff and Class Members are exposed to health risks associated with the revision as well as substantial care costs and income losses.

12. Class Members, including the Plaintiff, have experienced instability, swelling, inflammation, pain and stiffness that has impaired their ability to use their elbow/arm and otherwise perform their activities of daily living and employment. These complications have resulted in permanent injuries and the requirement of future surgery and care.

THE PLAINTIFF'S EXPERIENCE

13. On July 22, 2017, the Plaintiff sustained an injury to her right elbow and was seen at the Fracture Clinic of North York General Hospital on July 24, 2017, where X-Rays and a CT exam were performed. They revealed an acute displaced right radial head fracture with comminution.

14. On July 25, 2017, the Plaintiff underwent a right elbow radial head replacement and right elbow lateral ligament reconstruction. The surgery was performed by Dr. Peskun at the North York General Hospital. The implants used by Dr. Peskun were the EXPLOR 9x30 mm Stem Implant with Screw and the EXPLOR 14x24

mm Implant Head. The Plaintiff tolerated the procedure quite well and was discharged from the hospital on July 26, 2017.

15. Following her surgery, the Plaintiff returned to the Fracture Clinic of North York General Hospital on August 1, 2017, for a follow-up appointment with Dr. Peskun where repeat X-Rays were taken. They showed that the radial capitellar joint and elbow was well reduced.

16. On August 22, 2017, the Plaintiff's cast was removed and repeat X-Rays were taken at the Fracture Clinic of North York General Hospital by Dr. Peskun. The X-Rays indicated that the Device remained in a satisfactory position.

17. 10-weeks post-operation, the Plaintiff returned to the Fracture Clinic of North York General Hospital for a follow up appointment with Dr. Peskun, where no issues were present.

18. On January 17, 2020, the Plaintiff returned to Dr. Peskun at the Fracture Clinic of North York General Hospital with concerns surrounding her right elbow. An aspiration was performed that indicated there was no bacterial growth. However, on January 21, 2020, X-Rays were taken which indicated that the radial head has proximally migrated, and the locking screw had completely displaced. The X-Rays also showed concern for septic arthritis.

19. The Plaintiff underwent an initial revision surgery performed by Dr. Peskun on January 22, 2020, to remove the arthroplasty components and perform a right elbow radial osteotomy and synovectomy with implementation of antibiotic beads. The procedure went well, and the Plaintiff was admitted as an inpatient. She followed by the Infectious Disease team until she was discharged on January 24, 2020. At discharge, the Plaintiff was on antibiotics and had her right arm in a cast and sling.

20. In the two weeks following the surgery to remove the implant, the Plaintiff experienced swelling in her right hand and an infection which was treated with antibiotics.

21. The Plaintiff returned to the Fracture Clinic of North York General Hospital on March 3, 2020. An X-Ray taken Dr. Peskun showed destructive changes in the Plaintiff's humeroulnar joint with volar shift of the distal humerus, but otherwise was healing well from the surgery of January 22, 2020.

22. On May 11, 2020, Dr. Dantzer, along with Dr. Peskun and Dr. Mehdian, performed a right revision total elbow arthroplasty and right ulnar nerve transposition surgery on the Plaintiff. The pre-operative X-Rays taken showed evidence of prior radial head resection and severe arthritis at the ulnohumeral joint with valgus alignment, and the Plaintiff's joint was asymmetrical.

23. The Plaintiff returned to the Fracture Clinic of North York General Hospital on May 21, 2020, for follow up with Dr. Peskun. The Plaintiff was experiencing some pain which was treated with pain relief medication. An X-Ray taken at this appointment showed that the Plaintiff was healing well, although there was reduction in her range of motion. The Plaintiff was also referred to a physiotherapist.

24. On June 9, 2020, July 2, 2020, and October 13, 2020, the Plaintiff returned to the Fracture Clinic of North York General Hospital for follow up appointments with Dr. Peskun. During these appointments, Dr. Peskun noted that the Plaintiff was healing relatively well from the total arthroplasty, although overall improvement was limited.

25. Despite the Plaintiff's wound healing relatively well post-operatively since her total arthroplasty, she continues to experience a decrease in her range of motion, continued discomfort, and permanent scarring.

THE LIABILITY OF THE DEFENDANTS

Overview

26. The Corporate Defendants are liable to the Plaintiff and Class Members for all consequential damages incurred as a result of injuries to the Plaintiff and Class including economic and non-economic damages, past loss of income, future loss of earning capacity, pain, suffering, psychological and emotional distress,

medical expenses, medical treatment costs, hospitalization and rehabilitation costs, attendant care, nursing care, loss of earnings, punitive damages and costs and prejudgment interest.

27. The Plaintiffs state that they relied on the representations of the Defendants and had no way of knowing that the said Device used in their partial elbow replacement surgery was defective in design, manufacture and marketing, even when properly implanted by surgeons and/or healthcare providers.

28. Thousands of Class Members have or will experience ExploR Modular Radial Head System with ExploR Screw (trial number 418098, part number 11-210099) device failures, causing them to suffer and continue to suffer from emotional, physical and psychological injuries as a result of the Device failure and loosening implants, requiring medical attention and complicated revision surgeries to replace the defective Device. In addition, all recipients of these devices will suffer failure and future surgical revision and care as a result of this defective device.

29. At all times relevant to this action, the Corporate Defendants were engaged in the business of manufacturing, producing, inspecting, testing, packaging, warranting, distributing, selling and otherwise placing the Devices into the stream of commerce. The Devices were manufactured and used for the purpose of implantation in radial head replacement procedures and other related uses and the Corporate Defendants were the designers, manufacturers, testers, marketers,

sellers and/or distributors of the ExploR Modular Radial Head System with ExploR Screw (trial number 418098, part number 11-210099) device for use by ultimate consumers, including the Plaintiff.

30. The Plaintiff and Class Members directly or indirectly purchased the Devices manufactured by the Corporate Defendants through their distributors and/or healthcare providers to be used in the course of surgical procedures.

31. The Devices were defective and unreasonably dangerous, when sold, in that the screw loosens and/or backs out into the elbow cavity, despite proper implantation by the surgeons and/or healthcare providers and/or due to a foreseeable misuses of the Device attributable to the Corporate Defendants' faulty design, training or instruction and not due to any want of care by the Plaintiff.

Negligence/Breach of Contract/Breach of Statutory Warranties;

32. The Plaintiff says that aforesaid negligence and/or breach of contract of the Corporate Defendants or any or all of them, jointly and severally, and/or individually includes:

(a) The Device was defectively designed;

(b) The Device was defectively manufactured;

(c) The Device was not properly inspected. As a result of these design, manufacturing and testing failures there have been an unusually high rate of failures of all Device implants has and will continue to occur;

(d) The Device was not properly tested, designed or inspected to ensure that the device would be properly implanted and/or remain stabilized and positioned in place in the patients' elbow;

(e) The design of the Device provided no warning about tightness and/or torque limiter for surgeons to follow.

(f) Consumers and/or patients who were implanted with the Device would not have a reasonable opportunity or have the knowledge to inspect and/or understand how the Device would function once implanted and consequently had a high duty to ensure its reliability given its critical orthopedic function;

(g) They knew or ought to have known that the failure of the Device could or would result in serious health risks and consequences for patients but even after discovering the problems still sold the device for implantation;

(h) They knew or ought to have known that the Devices would be purchased by healthcare providers, physicians and/or patients for the purpose of elbow replacements and serious medical and operative procedures. The Device failed to function properly despite proper use of the Device by medical professionals trained to use it;

(i) The Device was inherently dangerous for its intended use due to the design and/or manufacturing defect and improper functioning. The Corporate Defendants and/or any of them used defective inspection and testing techniques and failed to institute proper quality control

testing in their production facilities which manufactures the Device;

(j) There were safer alternative designs which could have prevented or significantly reduced the risk of Device failure and displacement of the Device in patients;

(k) They failed to warn consumers/and or patients implanted with the Device of the inherent risks of their defectively designed, manufactured and inspected Device;

(l) The Device failed to properly remain fastened and resulted in loosening and/or displacement of the Device or parts of the Device while implanted inside the patients; and

(m) They failed to provide timely assistance or have equipment proximately available to replace or correct the defective equipment.

33. The Plaintiff and Class Members were not able to discover nor could they have discovered through exercise of reasonable care the defective nature of the Device. Further, in no way could they have known that the Corporate Defendants had designed, developed and manufactured the Device in such a way as to increase risk of harm or injury to the recipients of the Device.

Breach of Express and Statutory Warranties;

34. At all relevant times, the Defendants or any of them used advertising, publications and sales representatives to advertise and market the use and

purchase of the Device for use in elbow replacement procedures and/or related surgeries and expressly warranted that the Device improved the mobility, range of motion, and/or quality of life for thousands of individuals.

35. The Defendants or any of them expressly warranted that the Device would function efficiently similar to the natural articulation of radio-capitellar and radio-ulnar joints of the natural elbow. The Defendants expressly warranted to healthcare providers and/or patients that the Device was safe for implantation and/or use in patients.

36. By consenting to implantation of the Device, the Plaintiff and Class Members specifically relied on the skill and judgment of the Defendants and their express warranties and representations that the Device was safe for use.

37. The Defendants or any of them breached the express warranty by designing, manufacturing and marketing a defective product that failed to properly adhere and stay in place after implantation in the patient.

38. This defective product fails to comply with explicit warranties provided by the manufacturer as well as the implied warranties of fitness for intended purpose and merchantability in the *Sale of Goods Act*, R.S.O. 1990 C.S1 sections 14 and 15 as well as the provisions of the *Consumer Protection Act*, 2002, S.O. 2002, c.30 sections 14 and 15, as amended.

DAMAGES

39. The Plaintiffs and other putative Class Members' injuries and damages were caused by the negligence of the Defendants, their servants and their agents.

40. As a result of the Defendants' negligence, the Plaintiff has suffered and continues to experience serious personal injuries and harm with resultant pain and suffering.

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

42. 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 the various provincial health insurers.

43. The Plaintiff claims punitive, aggravated and exemplary damages for the reckless and unlawful conduct of the Defendants.

SERVICE OUTSIDE OF ONTARIO

44. The Plaintiff and class members rely on R.R.O. 1990, Regulation 195: *RULES*

OF CIVIL PROCEDURE R.S.O. under *Courts of Justice Act, R.S.O. 1990, c. C.43*, *Rule 17.02(f) and (g)* for service outside of Ontario.

PLACE OF TRIAL

45. The Plaintiffs propose the within action be Tried in the City of Toronto in the Province of Ontario.

Date: January 14, 2021

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LYNNE KOSS
Plaintiff

-and-

ZIMMER BIOMET HOLDINGS et al
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STATEMENT OF CLAIM

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