

CANADA  
PROVINCE OF QUÉBEC  
DISTRICT OF MONTRÉAL

SUPERIOR COURT OF QUÉBEC  
(CLASS ACTION)

No.: 500-06-000544-102

**MARGARET BÉATRICE OHANA DUNLOP**,  
residing and domiciled at [REDACTED]

[REDACTED];

*Petitioner*

vs.

**STRYKER CANADA LP**, a legal person duly  
constituted according to the laws of Canada,  
with offices being situated at [REDACTED]

[REDACTED];

and

**STRYKER CANADA CORP.**, a legal person  
duly constituted according to the laws of  
Canada, with offices being situated at [REDACTED]

[REDACTED];

and

**STRYKER CORPORATION**, a legal person  
duly constituted according to the law, with  
offices being situated at [REDACTED]

[REDACTED];

and

**STRYKER CANADIAN MANAGEMENT INC.**,  
a legal person duly constituted according to the  
laws of Canada, with offices being situated at [REDACTED]

[REDACTED];

and

**HOWMEDICA OSTEONICS CORPORATION**  
carrying on business as Stryker Orthopaedics,  
a legal person duly constituted according to the  
law, with offices being situated at [REDACTED]

*Respondents*

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**MOTION TO AUTHORIZE THE BRINGING OF A CLASS ACTION AND TO ASCRIBE  
THE STATUS OF REPRESENTATIVE  
(Art. 1002 C.C.P. and following)**

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**TO ONE OF THE HONOURABLE JUSTICES OF THE SUPERIOR COURT OF  
QUÉBEC, SITTING IN AND FOR THE DISTRICT OF MONTRÉAL, THE PETITIONER  
STATES THE FOLLOWING:**

**INTRODUCTION:**

1. Petitioner wishes to institute a class action on behalf of the following Group of which Petitioner is a member:

- All persons in Canada (including their estates, executors, personal representatives, their dependants and family members), who were implanted with a Stryker Trident PSL Cup or a Stryker Trident Hemispherical Acetabular Cup;

**ALTERNATELY (OR AS A SUBCLASS):**

- All persons in Québec (including their estates, executors, personal representatives, their dependants and family members), who were implanted with a Stryker Trident PSL Cup or a Stryker Trident Hemispherical Acetabular Cup;

(hereinafter referred to as the “**Class Members**”, the “**Class**”, the “**Group Members**”, the “**Group**”, “**Consumers**” or “**Users**” or “**Patients**”);

2. Respondents including their past and present related companies (hereinafter referred to collectively as “**Respondents**”), are companies that research, develop, design, test, manufacture, distribute, label, package, supply, market, advertise and sell various healthcare products;
3. At all material times the Respondents, Stryker Canada LP, Stryker Canadian Management Inc., Stryker Canada Corp., Stryker Corporation and Howmedica Osteonics Corporation (hereinafter collectively referred to as “**Stryker**”), carried on business inextricably interwoven with each other, and thus each Respondent is vicariously liable for the acts and omissions of the others. At all material times, Stryker carried on business and sold their products worldwide, including Québec and Canada;
4. Respondents sold and/or sell hip replacement systems, such as Stryker Trident PSL Cup, Stryker Trident Hemispherical Acetabular Cup or Stryker Trident Ceramic Acetabular System (hereinafter collectively referred to as the “**Hip Implants**” or the “**Hip Implant Systems**” or the “**Hip Replacement Systems**” or the “**Trident System**”), for the purpose of surgical procedures in which the hip joints are replaced by one of their prosthetic implants;
5. The Hip Implants are used to repair parts of the hip that are worn or weakened;
6. The Trident System was introduced in Canada in 1999;
7. The Respondents individually and collectively participated in one or more of: having researched, developed, designed, tested, manufactured, labeled, packaged, marketed, imported, distributed, promoted, and sold the Hip Implants;

8. The Hip Implants are Class III medical devices under the *Food and Drugs Act*, R.S.C. 1985, F-27;
9. After having one or more of the Hip Replacement Systems surgically implanted, numerous class members have reported chronic pain, repetitive clicking, popping, frequent swelling, a feeling that the implant has loosened, implant dislocation, bone fractures and fractures of the Hip Replacement Systems. Many of the class members have had to go back to have the Hip Replacement Systems surgically removed and replaced with models that are safer and more reliable. In some cases it has taken class members years to recover from having to undergo additional surgery;
10. The Respondents' Stryker Trident PSL Cup and Stryker Trident Hemispherical Acetabular Cup contain a ceramic-on-ceramic acetabular bearing couple, indicated for patients requiring primary total hip arthroplasty or replacement due to painful disabling joint disease of the hip resulting from non-inflammatory degenerative arthritis;
11. The Trident System is an artificial hip replacement prosthesis consisting of two components of a ceramic-on-ceramic acetabular bearing couple: an alumina ceramic insert (socket liner) and an alumina ceramic femoral head (ball). The Trident System is used with a metal acetabular shell (socket) and a metal femoral stem (hip stem);
12. The Trident System has been widely advertised and marketed by the Respondents as a safe and effective hip implant device and safer and longer lasting than other implant devices which use parts made from plastic and metal;

13. In early 2006, Stryker began receiving an unusually high number of complaints regarding problems with the Trident System. Amongst the problems experienced were pain, discomfort, improper wear of the joint implants and a squeaking sound coming from the implant;
14. On March 15, 2007, the United States' Food and Drug Administration (hereinafter the "**FDA**") issued a warning letter to Stryker arising from the FDA's inspections of Stryker's facilities in Cork, Ireland between October 31, 2006 and November 3, 2006. Prior to the delivery of this warning letter, the FDA inspector issued to Stryker a list of inspectional observations, which identified the following violations of federal regulations at Stryker's Ireland facilities:
  - a) Failure to establish and maintain adequate procedures for implementing a corrective and preventative action which included insufficient dwell time, nonconforming temperature, pressure variation, and burst test method variability;
  - b) Failure to establish and maintain adequate procedures to control product that fails to conform with specified requirements, including the evaluation of nonconforming products;
  - c) Failure to timely make changes to procedures to lessen confusion and better assure that root causes of nonconforming products are identified;
  - d) Failure to manufacture blister sealing used for sterilized products according to the federal requirements in that the blister sealing temperature, time, and pressure settings were outside of specified and validated operating parameters;
  - e) Failure to establish and maintain adequate procedures to implement and record changes in methods and procedures needed to correct and prevent identified

quality problems including failing to verify and implement changes to reduce the final rinse tank bioburden; and

- f) Failure to establish and maintain adequate procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications;

the whole as more fully appears from a copy of the March 15, 2007 letter (<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2007/ucm076326.htm>), communicated herewith, as **Exhibit R-1**;

- 15. On November 28, 2007, the FDA issued another letter to Stryker regarding problems at the New Jersey plant. The FDA found a number of production issues, including the presence of staph infection causing bacteria and other quality problems. The FDA also indicated that Stryker failed to adequately address reports of problems received between January 2005 and April 2007, the whole as more fully appears from a copy of the November 28, 2007 letter (<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2007/ucm076583.htm>), communicated herewith, as **Exhibit R-2**;
- 16. Furthermore, loosening causes severe pain to the Patients and renders the Trident System completely ineffective, thereby requiring Class Members to undergo hip revision surgery;
- 17. Stryker failed to adequately warn patients, doctors and Health Canada of the risk of loosening in the Trident System;
- 18. Despite claims by Stryker that rate of squeaking is 0.5% of Patients who are implanted with the Trident System, the whole as more fully appears from a copy of a statement from the Stryker website (<http://www.aboutstryker.com/labeling/>),

communicated herewith, as **Exhibit R-3**, the American Association of Hip and Knee Surgeons reported in 2009 that a more accurate rate of squeaking is 35.6%, the whole as more fully appears from a copy of the abstract of the study by the American Association of Hip and Knee Surgeons (<http://www.ncbi.nlm.nih.gov/pubmed/20663638>), communicated herewith, as **Exhibit R-4**;

19. On January 22, 2008, Stryker initiated a recall on the Trident System, the whole as more fully appears from copies of Stryker's Press Releases (<http://www.stryker.com/en-us/biomed/031068>), communicated herewith, as **Exhibit R-5**;

#### **FACTS GIVING RISE TO AN INDIVIDUAL ACTION BY THE PETITIONER**

20. The Petitioner, **MARGARET PEGGY OHANA DUNLOP**, is 63 years old and resides in the City of Laval-des-Rapides, Québec;
21. On or about March 31, 2008, the Petitioner had a Stryker Trident implant surgically inserted in her left hip at the Notre-Dame Hospital in Montréal, Québec and she then convalesced at the Jewish Hospital Rehabilitation Centre, in Laval, Québec, for fifteen (15) days where she also had daily physiotherapy treatments;
22. Since Petitioner's Hip Implant surgery, she developed and has been suffering from constant general pain in her left leg and groin and stiffness;
23. Following Petitioner's Hip Implant surgery, Petitioner developed a bump on her hip for which she had to undergo two (2) punctures at the Notre-Dame Hospital in Montréal, Québec;

24. When Petitioner stands for a few minutes without walking, her left leg stiffens and she then limps when starting to walk again;
25. Not only did Petitioner's pain not disappear after her Hip Implant surgery, but it has worsened and has restricted her from her usual activities, such as walking, dancing;
26. Since her Hip Implant surgery, Petitioner is unable to walk normally without being forced to stop frequently, she requires support railing on both sides in order to go up stairs, and she suffers from constant inflammation in the hip area;
27. Petitioner may have to undergo a revision of her Hip Implant due to the existing, constant and present pain resulting from the implant of the now recalled Stryker System;
28. Respondents failed to warn the Petitioner (and other Class Members), prior to the surgery, of the health risks posed by the Hip Implants;
29. Had the Respondents issued warnings, the Petitioner (and other Class Members) would not have used the Hip Implants;

**FACTS GIVING RISE TO AN INDIVIDUAL ACTION BY EACH OF THE MEMBERS OF THE GROUP**

30. Respondents researched, designed, tested, manufactured, marketed, labeled, distributed, promoted and sold Hip Implants in many countries including Canada;
31. At all material times, Respondents have marketed that Hip Implants are safe and beneficial, which is not true;



32. Respondents warranted and represented that the Hip Implants were fit for their use by Consumers and posed no significant health risks to those Users;
33. The Hip Implants are associated with increased negative health effects including but not limited to increased risk for hip revision surgery, decreased mobility, back pain, leg pain, hip pain, groin pain, and/or other risks or side effects mentioned hereinabove;
34. The Class Members have incurred injuries and losses from the use of the Hip Implants, including expenses relating to medical treatment sought and received, physical injuries, opportunity costs incurred as a result of illness or visits to medical facilities, loss of employment income, loss of enjoyment of life, pain and suffering, and anticipated future medical and health costs;
35. The Class Members have suffered and will continue to suffer physical injuries and other losses, or damages due to the Hip Implants, and claim damages as a result;
36. Had the Respondents done appropriate scientific research and testing, as well as carried out reviews of related medical journals or studies, they should have known that Hip Implants materially contribute to the risk of serious adverse medical events as described above and should have fully informed the medical professionals and Consumers, including the Petitioner and putative Class Members, of such risks in a timely manner;
37. Respondents knew or should have known of the risks from the use of the Hip Implants but portrayed Hip Implants as a safe and effective solution to helping those with weak or worn hips;

38. Had the true facts been disclosed that Hip Implants are associated with devastating side effects, Consumers would not have used the Hip Implants;
39. Respondents misled or deceived Class Members by representing that Hip Implants do not pose the aforesaid risks to them during normal use;
40. Respondents warranted that Hip Implants were safe and fit for their intended and foreseeable purpose. However, Hip Implants were not, and are not, safe for their intended use in that they pose an undue risk of harm to the Members of the Class;
41. At all material times, Respondents failed to provide the medical community and the general public with a clear, complete, and current warning of the risks associated with Hip Implants' use, or failed to provide such warning in a timely manner, and Respondents were negligent in that regard;
42. Furthermore, or in the alternative, Respondents did inferior research, design, and tests on Hip Implants and therefore made defective products;
43. Had the true facts been disclosed that the Hip Implants are associated with increased negative health effects including but not limited to increased risk for hip revision surgery, decreased mobility, back pain, leg pain, hip pain, groin pain, and/or other risks or side effects, the use of said Hip Implants on an objective Class wide basis would not have occurred and the Class Members would not have experienced the aforementioned injuries or health risks;
44. Consumers reasonably relied and rely upon the Respondents to ensure that the Hip Implants were safe for their intended use;

45. Respondents are liable for the damages suffered by the Petitioner and the Class Members in that Respondents failed to use sufficient quality control, to conduct adequate testing, and to perform proper manufacturing, production, or processing, or failed to take sufficient measures to prevent harmful Hip Implants from being offered for sale, sold or used by Consumers, when they knew or ought to have known about the serious health risks but still sold and distributed their Hip Implants in Canada;
46. As a direct and proximate result of the Respondents' negligence, the Class Members suffered pain, damages, injuries and risks for which the Respondents are solely liable;
47. Through their recall, Respondents have admitted the defects affecting the Hip Implants;
48. Each Member of the Group is entitled to claim damages because of the faults and/or negligence of the Respondents, which include but are not limited to personal injuries suffered, economic and financial losses (i.e. loss of income and earning capacity), pain and suffering, loss of amenities and enjoyment of life, costs of past and future care and related expenses, such further and other damages, the particular of which may be proven at trial on the merits;
49. Moreover, the Respondents' conduct, through actions, omissions, wrongdoings, and their awareness of the serious hazards of said Hip Implants, and their failure to fully, clearly, and in a timely way disclose and publicize the serious health effects resulting from the use of the Hip Implants (all detailed hereinabove), subject the Respondents to punitive and/or exemplary damages;

**CONDITIONS REQUIRED TO INSTITUTE A CLASS ACTION**

50. The composition of the Group makes the application of Article 59 or 67 C.C.P. impractical for the following reasons:

- a) The number of potential Group Members is so numerous that joinder of all Members is impracticable. While the exact number of Group Members is unknown to Petitioner at the present time and can only be ascertained from sales and distribution records maintained by the Respondents and their agents, it can be reasonably estimated that there are thousands of potential Group Members located throughout Canada;
- b) Based on the number of potential Group Members, it is impossible for the Petitioner to identify all potential Group Members and obtain a mandate from each of them. Petitioner does not possess the names and addresses of potential Group Members;

51. The recourses of the members raise identical, similar or related questions of fact or law, namely:

- a) Do the Hip Implants cause an increase in negative health effects, and to what extent?
- b) Were the Hip Implants unsafe, or unfit for the purpose for which they were intended as designed, developed, manufactured, sold, distributed, marketed or otherwise placed into the stream of commerce by the Respondents?
- c) Were Respondents negligent or did they commit faults in the designing, developing, testing, manufacturing, marketing, distributing, labelling or selling of the Hip Implants?

- d) Did Respondents fail to inform the Class Members of the health risks associated with the use of Hip Implants?
  - e) Are Respondents liable to pay damages to the Group Members as a result of their faults, negligence, or misrepresentations made in manufacturing, marketing, distributing or selling of the Hip Implants, or as a result of the use of Hip Implants?
  - f) Are Respondents liable to pay compensatory damages to the Group Members, and if so in what amount?
  - g) Are Respondents liable to pay moral damages to the Group Members, and if so in what amount?
  - h) Are Respondents liable to pay exemplary or punitive damages to the Group Members, and if so in what amount?
52. The majority of the issues to be dealt with are issues common to every Group Member;
53. The interests of justice favour that this motion be granted in accordance with its conclusions;

**NATURE OF THE ACTION AND CONCLUSIONS SOUGHT**

54. The action that Petitioner wishes to institute for the benefit of the Members of the Group is an action in damages for product liability;
55. The conclusions that Petitioner wishes to introduce by way of a motion to institute proceedings are:

**GRANT** Petitioner's action against Defendants;

**CONDEMN** Defendants to pay an amount in compensatory damages to the Group Members, amount to be determined by the Court, plus interest as well the additional indemnity;

**CONDEMN** Defendants to pay an amount in moral damages to the Group Members, amount to be determined by the Court, plus interest as well the additional indemnity;

**CONDEMN** Defendants to pay an amount in punitive and/or exemplary damages to the Group Members, amount to be determined by the Court, plus interest as well the additional indemnity;

**GRANT** the class action of Petitioner on behalf of all the Members of the Group;

**ORDER** the treatment of individual claims of each Member of the Group in accordance with Articles 1037 to 1040 C.C.P.;

**THE WHOLE** with interest and additional indemnity provided for in the *Civil Code of Québec* and with full costs and expenses including experts' fees and publication fees to advise members.

56. Petitioner suggests that this class action be exercised before the Superior Court in the District of Montréal for the following reasons:
- a) Petitioner was surgically implanted with a Hip Implant in the District of Montréal;
  - b) Respondents sell the Hip Implants in the District of Montréal;

- c) Many Group Members are domiciled or work in the District of Montréal;
- d) Respondent Stryker Canadian Management Inc. has offices in the District of Montréal;
- e) Petitioner's legal counsel practice law in the District of Montréal.

57. Petitioner, who is requesting to obtain the status of representative, will fairly and adequately protect and represent the interest of the members of the Group since Petitioner:

- a) Was surgically implanted a Hip Implant without being made aware of the health risks associated with the use of said devices;
- b) suffered damages and injuries from using Hip Implants, as detailed above;
- c) understands the nature of the action and has the capacity and interest to fairly and adequately protect and represent the interests of the Members of the Group;
- d) is available to dedicate the time necessary for the present action before the Courts of Québec and to collaborate with Class attorneys in this regard;
- e) is ready and available to manage and direct the present action in the interest of the Class Members that Petitioner wishes to represent, and is determined to lead the present file until a final resolution of the matter, the whole for the benefit of the Class;
- f) does not have interests that are antagonistic to those of other members of the Group;
- g) has given the mandate to the undersigned attorneys to obtain all relevant information to the present action and intends to keep informed of all developments;

- h) is, with the assistance of the undersigned attorneys, ready and available to dedicate the time necessary for this action and to collaborate with other Members of the Group and to keep them informed;

58. The present motion is well founded in fact and in law.

**FOR THESE REASONS, MAY IT PLEASE THE COURT:**

**GRANT** the present Motion;

**ASCRIBE** the Petitioner the status of representative of the persons included in the Group herein described as:

- All persons in Canada (including their estates, executors, personal representatives, their dependants and family members), who were implanted with a Stryker Trident PSL Cup or a Stryker Trident Hemispherical Acetabular Cup;

**ALTERNATELY (OR AS A SUBCLASS):**

- All persons in Québec (including their estates, executors, personal representatives, their dependants and family members), who were implanted with a Stryker Trident PSL Cup or a Stryker Trident Hemispherical Acetabular Cup;

**IDENTIFY** the principle questions of fact and law to be treated collectively as the following:



- a) Do the Hip Implants cause an increase in negative health effects, and to what extent?
- b) Were the Hip Implants unsafe, or unfit for the purpose for which they were intended as designed, developed, manufactured, sold, distributed, marketed or otherwise placed into the stream of commerce by the Respondents?
- c) Were Respondents negligent or did they commit faults in the designing, developing, testing, manufacturing, marketing, distributing, labelling or selling of the Hip Implants?
- d) Did Respondents fail to inform the Class Members of the health risks associated with the use of Hip Implants?
- e) Are Respondents liable to pay damages to the Group Members as a result of their faults, negligence, or misrepresentations made in manufacturing, marketing, distributing or selling of the Hip Implants, or as a result of the use of Hip Implants?
- f) Are Respondents liable to pay compensatory damages to the Group Members, and if so in what amount?
- g) Are Respondents liable to pay moral damages to the Group Members, and if so in what amount?
- h) Are Respondents liable to pay exemplary or punitive damages to the Group Members, and if so in what amount?

**IDENTIFY** the conclusions sought by the class action to be instituted as being the following:

**GRANT** Petitioner's action against Defendants;

**CONDEMN** Defendants to pay an amount in compensatory damages to the Group Members, amount to be determined by the Court, plus interest as well the additional indemnity;

**CONDEMN** Defendants to pay an amount in moral damages to the Group Members, amount to be determined by the Court, plus interest as well the additional indemnity;

**CONDEMN** Defendants to pay an amount in punitive and/or exemplary damages to the Group Members, amount to be determined by the Court, plus interest as well the additional indemnity;

**GRANT** the class action of Petitioner on behalf of all the Members of the Group;

**ORDER** the treatment of individual claims of each Member of the Group in accordance with Articles 1037 to 1040 C.C.P.;

**THE WHOLE** with interest and additional indemnity provided for in the *Civil Code of Québec* and with full costs and expenses including experts' fees and publication fees to advise members.

**DECLARE** that all Members of the Group that have not requested their exclusion from the Group in the prescribed delay to be bound by any judgment to be rendered on the class action to be instituted;

**FIX** the delay of exclusion at thirty (30) days from the date of the publication of the notice to the Members;

**ORDER** the publication of a notice to the Members of the Group in accordance with Article 1006 C.C.P. and **ORDER** Respondents to pay for said publication costs;

**THE WHOLE** with costs to follow.

**MONTRÉAL, December 10, 2010**

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**MERCHANT LAW GROUP LLP**  
Attorneys for Petitioner