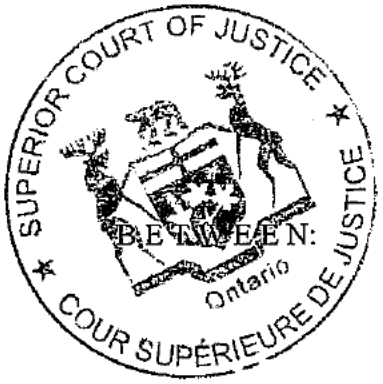


Court File No.
17-72462-CP

ONTARIO
SUPERIOR COURT OF JUSTICE

P[redacted] MCWILLIAMS

Plaintiff

- and -

BARD CANADA INC., C.R. BARD, INC., BARD ASDI, INC., DAVOL INC., GENZYME CANADA INC., AND GENZYME CORPORATION (ALSO DOING BUSINESS AS **GENZYME BIOSURGERY**)

Defendants

Proceeding under the Class Proceedings Act, 1992

STATEMENT OF CLAIM

TO THE DEFENDANTS

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the plaintiff. 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.

TAKE NOTICE: THIS ACTION WILL AUTOMATICALLY BE DISMISSED if it has not been set down for trial or terminated by any means within five years after the action was commenced unless otherwise ordered by the court.

Date: April 28, 2017

Issued by

Local Registrar

Address of court office: 161 Elgin Street
2nd Floor
Ottawa, ON K2P 2K1

TO: **Bard Canada Inc.**
2715 Bristol Circle #1
Oakville, Ontario
L6H 6X5

AND TO: **C.R. Bard, Inc.**
730 Central Avenue
New Providence, New Jersey
07974, USA

AND TO: **Bard ASDI, Inc.**
730 Central Avenue
New Providence, New Jersey
07974, USA

AND TO: **Davol Inc.**
100 Crossing Boulevard
Warwick, Rhode Island
02886, USA

AND TO: **Genzyme Canada Inc.**
2700 Matheson Boulevard East, Suite 800
Mississauga, Ontario
L5W 4V9

AND TO: **Genzyme Corporation**
500 Kendall Street
Cambridge, Massachusetts
02142, USA

DEFINED TERMS

1. In this Statement of Claim, in addition to the terms that are defined elsewhere herein, the following terms have the following meanings:

(a) "**Hernia Mesh Device(s)**" include all of the **Defendants'** hernia mesh products designed with polypropylene[1], which include, but are not limited to (and solely by way of examples):

(i) The Kugel Hernia Mesh Patch,

(ii) The 3DMax Mesh,

(iii) The PerFix Plug,

(iv) The Ventralex Hernia Mesh and the Ventralex ST Hernia Mesh, and

(v) The Sepramesh Composite;

(b) The "**Hernia Mesh Injuries**" and/or the "**Dangerous Complications**" include, but are not limited to the following injuries and complications caused by the **Hernia Mesh Devices**:

(i) Mesh erosion, contraction, and/or degradation;

(ii) Infection, including sepsis and gangrene (an infected hernia mesh almost always requires removal);

[1] A cheap plastic mainly used in packaging and labeling, textiles, stationary, plastic parts, reusable containers, etc.

(iii) Adhesions (connecting the bowel to the hernia mesh. Adhesions frequently form when ventral hernias are repaired with a coated mesh such as Ventralex ST Hernia Mesh and the Sepramesh);

(iv) Perforation of bowel or other organs;

(v) Bowel obstruction (inability to defecate);

(vi) Diarrhea (early symptom of the mesh attaching to the bowel);

(vii) Constipation (sign of a bowel obstruction);

(viii) Difficulty or inability to urinate,

(ix) Chronic abdominal pain;

(x) Allergic reactions, including rashes (commonly observed in association with coated hernia meshes);

(xi) Leg, groin, and testicular pain (often debilitating);

(xii) Pain with sex (dyspareunia);

(xiii) Rejection and foreign body response to the polypropylene;

(xiv) Amputation, including testicular removal;

(xv) Slow healing wounds;

(xvi) Ulcers;

(xvii) Blood loss;

(xviii) Nausea (sign of adhesions to the bowel and/or stomach);

(xix) Seroma (a fluid capsule surrounding the mesh);

(xx) Fistulas[2];

(xxi) Dental pain, infections, rotting and/or loss of teeth;

(xxii) Autoimmune disorders;

(xxiii) Neurological changes;

(xxiv) Severe headaches;

(xxv) Fever (often associated with both an autoimmune response to the mesh and infection);

(xxvi) Renal failure (associated with large coated meshes; the coatings are absorbable and put a great deal of strain on the kidneys);

(xxvii) Liver abnormalities (associated with coated hernia meshes);

(xxviii) Joint aches and pain can be caused by increased systemic inflammation due to infection and an autoimmune reaction to the mesh;

(xxix) Abnormal perspiration (related to an autoimmune response or infection);

[2] A fistula is an abnormal tunnel between two structures. Many fistulas connect to the bowel, which are associated with infections.

(xxx) Meshoma (migration, contracture, or bunching-up of an artificial mesh, which become hard, tumor-like bodies);

(xxxi) Chronic nerve damage;

(xxxii) Chronic hernia-related pain;

(xxxiii) Surgical correction/ implant revision surgery;

(xxxiv) Permanent disability;

(xxxv) Physical pain and mental anguish;

(xxxvi) Physical impairment and/or disfigurement; and/or

(xxxvii) Death;

(c) "**Design Defect**" and/or "**Product Defect**" means (i) the design of the **Hernia Mesh Devices** with polypropylene, a cheap plastic material that has a propensity to contract, retract, shrink, degrade, and/or fragment inside the body after surgical implantation and (ii) the design of many of the **Hernia Mesh Devices** with a "bioresorbable coating", which causes severe inflammatory, allergic, and autoimmune reactions in humans – both of which cause the **Hernia Mesh Injuries**;

(d) "**U.S. FDA**" means the United States Food and Drug Administration;

(e) "**Class**", "**Proposed Class**", and/or **"Class Members**" means all persons residing in Canada, excluding Quebec, who were surgically implanted with a **Hernia Mesh Device**

and their successors, assigns, family members, and dependants, or any other group to be determined by the Court;

(f) "***Courts of Justice Act***" means the *Ontario Courts of Justice Act*, RSO 1990, c. C-43, as amended;

(g) "***Class Proceedings Act***" means the *Class Proceedings Act*, 1992, SO 1992, c. 6, as amended;

(h) "***Competition Act***" means the *Competition Act*, RSC 1985, c. C-34, as amended;

(i) "***Food and Drugs Act***" means the *Food and Drugs Act*, RSC 1985, c. F-27, as amended;

(j) "***Health Insurance Act***" means the *Health Insurance Act*, RSO 1990, c.11.6, as amended;

(k) "**Defendants**" means Bard Canada Inc., C.R. Bard, Inc., Bard ASDI, Inc., Davol Inc., Genzyme Canada Inc., and Genzyme Corporation (also doing business as Genzyme Biosurgery; and

(l) "**Representative Plaintiff**" or "**Plaintiff**" means P[redacted] McWillams;

THE CLAIM

2. The proposed Representative Plaintiff, P[redacted] McWilliams, claims on his own behalf and on behalf of the members of the Class of persons as defined in paragraphs 4 below (the "Class") as against Bard Canada Inc., C.R. Bard, Inc., Bard ASDI, Inc., Davol Inc., Genzyme Canada Inc., and Genzyme Corporation (the "Defendants"):

(a) An order pursuant to the *Class Proceedings Act* certifying this action as a class proceeding and appointing him as Representative Plaintiff for the Class Members;

(b) A declaration that the Defendants are strictly liable for all of the damages suffered by the Class Members;

(c) A declaration that the Defendants were negligent in the research, development, design, manufacturing, testing, production, supply, marketing, labelling, packaging, promotion, advertising, importation, distribution, and/or sale of the Hernia Mesh Devices;

(d) A declaration that the Defendants breached their express and/or implied warranties relating to their representation regarding the Hernia Mesh Device's safety, fitness, and merchantability for its intended uses/purposes;

(e) A declaration that the Defendants breached their duty to warn the Plaintiff and Class Members of the Dangerous Complications associated with the Hernia Mesh Devices;

(f) A declaration that the Defendants committed a fraudulent and/or negligent misrepresentation when they represented to the medical and health community, to Health Canada, to the Plaintiff, to the Class Members, and to the public in general that the Hernia Mesh Devices had been tested and found to be safe and effective for surgical implantation;

(g) A declaration that the Defendants made materially false and/or misleading representations/omissions for the purposes of promoting the supply of the Hernia Mesh Devices and their own business interests, in contravention of the *Competition Act*;

(h) A declaration that the Defendants breached the *Food and Drugs Act* in selling the Hernia Mesh Devices that caused injury to the health of the users and in labelling, packaging, selling, and advertising the Hernia Mesh Products in a manner that is false, misleading and/or deceptive or is likely to create an erroneous impression regarding its design, construction, performance, intended use, character, composition, merit, and/or safety;

(i) A declaration that the Defendants are vicariously liable for the acts and omissions of their officers, directors, agents, employees, and representatives;

(j) A declaration that the Defendants are jointly and severally liable for any and all damages awarded;

(k) General damages in an amount to be assessed individually or in the aggregate for the Class Members for, *inter alia*, the Dangerous Complications, including pain and suffering, loss of enjoyment of life, embarrassment/humiliation, stress/distress, anxiety/anguish, trouble, and inconvenience;

(l) Special damages in an amount that this Honourable Court deems appropriate, to compensate Class Members for, *inter alia*, out-of-pocket expenses incurred or to be

incurred, including those connected with hospital stays, medical treatment, life care, medications, medical monitoring services, the diagnosis and treatment of the Dangerous Complications, loss of income, loss of future income, and the purchase price of medications purchased or alternatively the incremental costs paid pursuant to the Ontario Health Insurance Plain (and/or other provincial health insurers);

(m) Punitive (exemplary) and aggravated damages in an amount to be determined as this Honourable Court deems appropriate;

(n) In the alternative to the claim for damages, a restitutionary remedy disgorging the revenues realized by the Defendants from the sales of the Hernia Mesh Devices in Canada, such as: (i) an order for an accounting of revenues received by the Defendants and/or (ii) a declaration that any funds received by the Defendants through the sale of all of the Hernia Mesh Devices in Canada are held in trust for the benefit of the Plaintiff and Class Members;

(o) Restitution and/or a refund of all monies paid to or received by the Defendants from the sale of all the Hernia Mesh Devices in Canada on the basis of unjust enrichment;

(p) In addition, or in the alternative, restitution and/or a refund of all monies paid to or received by the Defendants from the sale of all the Hernia Mesh Devices in Canada on the basis of *quantum valebant*;

(q) An order compelling the creation of a plan of distribution pursuant to ss. 23, 24, 25 and 26 of the *Class Proceedings Act*;

(r) An interim interlocutory and permanent order restraining the Defendants from continuing any tortious actions, including those taken in contravention of the law, whether statutory, and/or equitable;

(s) A mandatory order requiring the Defendants to recall the Hernia Mesh Devices;

(t) 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;

(u) Pre-judgment and post-judgment interest on the foregoing sums in the amount of 2% per month, compounded monthly, or alternatively, pursuant to ss. 128, 129, and 130 of the *Courts of Justice Act*;

(v) Costs of notice and administration of the plan of distribution of recovery in this action, plus applicable taxes, pursuant to s. 26 (9) of the *Class Proceedings Act*;

(w) Costs of this action on a substantial indemnity basis including any and all applicable taxes payable thereon; and

(x) Such further and other relief as counsel may advise and/or this Honourable Court may deem just and appropriate in the circumstances.

THE PARTIES

The Representative Plaintiff

3. The Plaintiff, P[redacted] McWilliams, is an individual residing in the city of Norval, in the province of Ontario. In December 2003, Mr. McWilliams underwent a hernia repair surgery at the

Credit Valley Hospital at 2200 Eglinton Avenue West, in Mississauga, Ontario, during which time he was surgically implanted with a Hernia Mesh Device.

The Class

4. The Plaintiff, Mr. McWilliams seeks to represent the following class of which he is a member (the "Proposed Class"):

> All persons residing in Canada, excluding Quebec, who were surgically implanted with a Hernia Mesh Device and their successors, assigns, family members, and dependants.

The Defendants

5. The Defendant, Bard Canada Inc. ("Bard Canada"), is a Canadian corporation with its head office in Oakville, Ontario. Bard Canada is and was at all relevant times involved in the research, development, design, manufacture, testing, production, supply, marketing, labelling, packaging, promotion, advertising, importation, distribution, and/or sale of medical devices including the Hernia Mesh Devices. It is a wholly-owned subsidiary of Defendant C.R. Bard, Inc. that does business throughout Canada, including within the province of Ontario.

6. The Defendant, C.R. Bard, Inc. ("C.R. Bard"), is an American corporation with its head office in New Jersey. C.R. Bard is and was at all relevant times involved in the research, development, design, manufacture, testing, production, supply, marketing, labelling, packaging, promotion, advertising, importation, distribution, and/or sale of medical devices including the Hernia Mesh Devices. It is the parent company of Defendants Bard Canada, Bard ASDI, Inc., and Davol, Inc. It is the registrant of the trade-mark "BARD" (TMA149832), which was filed on March 22, 1966, the trade-mark "PERFIX" (TMA517987), which was filed on September 17, 1996, the

trade-mark “3DMAX” (TMA564417), which was filed on June 22, 1999, the trade-mark “KUGEL” (TMA584972), which was filed on June 15, 2000, and the trade-mark “VENTRALEX” (TMA617962), which was filed on June 25, 2002.

7. Defendant Bard ASDI, Inc. (“Bard ASDI”) is an American corporation with its head office in New Jersey. Bard ASDI is and was at all relevant times involved in the research, development, design, manufacture, testing, production, supply, marketing, labelling, packaging, promotion, advertising, importation, distribution, and/or sale of medical devices including the Hernia Mesh Devices. It is a wholly-owned subsidiary of Defendant C.R. Bard. It is the owner of the patent “HERNIA MESH PATCH” (CA 2201439), which was filed on April 1, 1997.

8. The Defendant, Davol Inc. (“Davol”), is an American corporation with its head office in Rhode Island. Davol is and was at all relevant times involved in the research, development, design, manufacture, testing, production, supply, marketing, labelling, packaging, promotion, advertising, importation, distribution, and/or sale of medical devices including the Hernia Mesh Devices. It is a wholly-owned subsidiary of Defendant C.R. Bard.

9. Defendant Davol holds (or has held) the license from Health Canada to manufacture the following medical devices:

a) “BARD MESH PRODUCTS” (5688), which was first issued on June 16, 1999,

b) “BARD MESH PRODUCTS” (10850), which was first issued on August 27, 1999 and was revoked on October 31, 2000,

c) The “BARD MESH – PERFIX PLUG” Plug (10948), which was first issued on August 30, 1999,

d) The “KUGEL HERNIA PATCH” (20585), which was first issued on May 17, 2000,

e) The “BARD 3DMAX MESH” (23481), which was first issued on November 2, 2000,

f) The “BARD COMPOSIX E/X MESH” (35759), which was first issued on January 18, 2002,

g) “COMPOSIX KUGEL MESH” (37316), which was first issued on April 10, 2002 and revoked on June 27, 2013,

h) The “BARD VENTRALEX HERNIA PATCH” (62901), which was first issued on August 14 2003 and then again on January 22, 2007,

i) The “BARD MODIFIED KUGEL HERNIA PATCH, CIRCLE” (65705), which was first issued on August 31, 2004,

j) “BIORESORBABLE COATING/PERMANENT MESH” (83022), which was first issued on July 6, 2011 and revoked on July 6, 2011, and

k) The “VENTRALEX ST HERNIA PATCH” (62901), which was first issued on March 13, 2012,

10. The Defendant, Genzyme Canada Inc. (“Genzyme Canada”) is a Canadian Corporation with its head office in Mississauga, Ontario. Genzyme Canada is and was at all relevant times involved in the research, development, design, manufacture, testing, production, supply, marketing, labelling, packaging, promotion, advertising, importation, distribution, and/or sale of

medical devices including the Hernia Mesh Device, the Sepramesh. It does business throughout Canada, including within the province of Ontario.

11. The Defendant, Genzyme Corporation, is an American corporation with its head office in Massachusetts. Genzyme Corporation is and was at all relevant times involved in the research, development, design, manufacture, testing, production, supply, marketing, labelling, packaging, promotion, advertising, importation, distribution, and/or sale of medical devices including the Hernia Mesh Device, the Sepramesh. It is the registrant of the trade-mark "SEPRAFILM" (TMA490736), which was filed on March 19, 1997 and the trade-mark "SEPRAMESH" (TMA660076), which was filed on February 15, 2005.

12. Defendant Genzyme Corporation organized its business into several unincorporated business units, one of which was Genzyme Biosurgery, which was responsible for the sale, marketing, and promotion of the Seprafilm adhesion barrier, which is composed of the same material as the bioresorbable coating on the Sepramesh. It is also held the license to manufacture the "SEPRAMESH BIOSURGICAL COMPOSITE" (20687), which was first issued on May 29, 2000 – the license was revoked on November 5, 2007 and the "SEPRAMESH IP" (66916), which was first issued on December 23, 2004 – the license was revoked on October 29, 2010.

13. On December 17, 2007, Defendant C.R. Bard entered into a license agreement with Defendant Genzyme Corporation to manufacture and market the Sepramesh IP Hernia Mesh and to incorporate the Sepra coating technology into the development of future hernia repair applications.

14. Given the close ties between the Defendants and considering the preceding, they are all jointly and severally liable for the acts and omissions of the other.

THE NATURE OF THE CLAIM

15. The Defendants are and, have been at all relevant times, engaged in the business of researching, developing, designing, manufacturing, testing, producing, supplying, marketing, labelling, packaging, promoting, advertising, importing, distributing, and/or selling the Hernia Mesh Devices which are the subject of the present Statement of Claim.

16. As will be elaborated upon hereinbelow, the Hernia Mesh Devices are designed and/or intended for surgical implantation in humans in order to repair hernias[3], by either patching the weakness in the abdominal wall or plugging the hole;

17. Unfortunately, the Hernia Mesh Devices are defective in that they are developed, designed, manufactured, produced, and supplied with: (i) polypropylene, a cheap plastic material that has a propensity to contract, retract, shrink, degrade, and/or fragment inside the body after surgical implantation and (ii) many of the Hernia Mesh Devices were coated with a "bioresorbable coating", which causes severe inflammatory, allergic, and autoimmune reactions in humans and causing the Hernia Mesh Injuries (together the "Product Defects" and/or the "Design Defects").

[3] As will be described in more detail hereinbelow, hernia occurs when an organ or fatty tissue squeezes through a weak spot in a surrounding muscle or connective tissue called fascia. The most common types of hernia are inguinal (inner groin), incisional (resulting from an incision), femoral (outer groin), umbilical (belly button), and hiatal (upper stomach).

18. Therefore, and quite ironically, while the Hernia Mesh Devices are marketed as devices to prevent pain and other medical complications related to a hernia, it may actually achieve the opposite; actively increasing the risk of Hernia Mesh Injuries and Dangerous Complications due to the Design Defect.

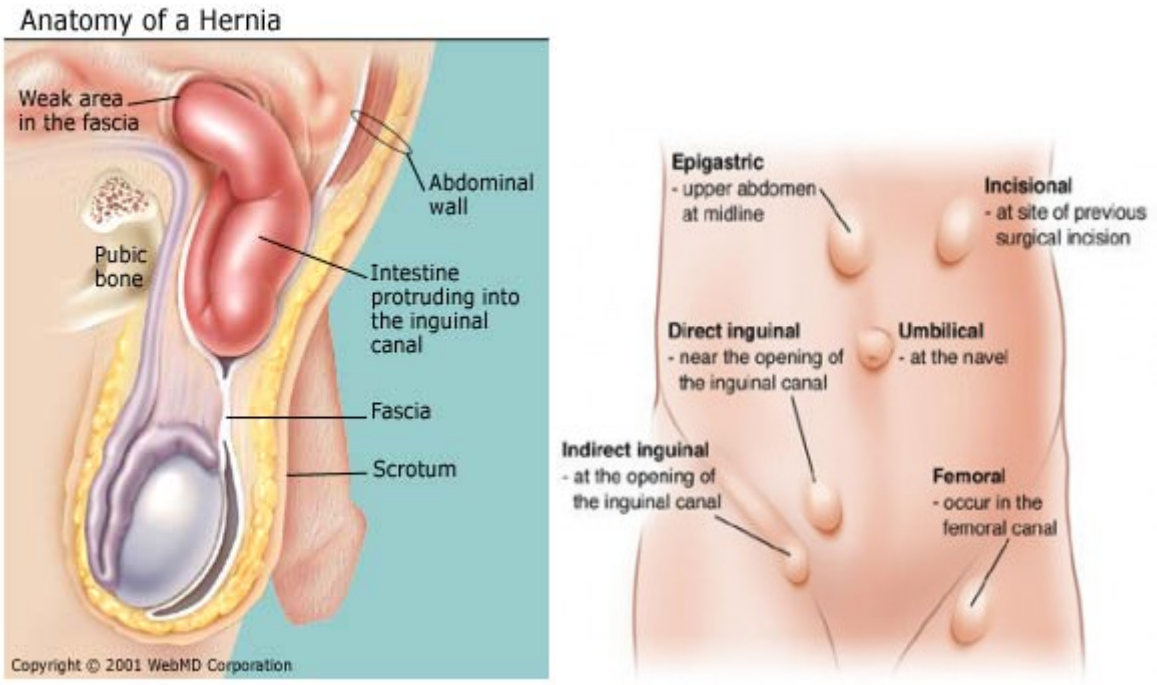
19. The Defendants represented to the medical and healthcare community, to Health Canada, and to the Class Members that they researched, developed, designed, manufactured, tested, produced, supplied, and manufactured the Hernia Mesh Devices and that they had been found to be safe and/or effective for their intended use. In addition, the Defendants concealed their knowledge of the Hernia Mesh Device's defects from the medical and healthcare community, Health Canada, and from Class Members.

20. Defendants failed to disclose, despite a wealth of longstanding knowledge, that the use of Hernia Mesh Devices significantly increased the risk of Hernia Mesh Injuries and/or the Dangerous Complications.

21. The Defendants continue to manufacture, produce, supply, market, label, package, promote, advertise, import, distribute, and/or sell the Hernia Mesh Devices throughout Canada, including within the province of Ontario, with inadequate warnings as to its serious and adverse side effects.

I. Hernias – Explained

22. A hernia occurs when an organ or fatty tissue squeezes through a weak spot in a surrounding muscle or connective tissue called fascia. The most common types of hernia are inguinal (inner groin), ventral (abdominal, including umbilical), incisional (resulting from a previous incision or scar), femoral (outer groin), and hiatal (upper stomach).



23. A bilateral hernia is a type of inguinal or groin hernia that occurs in both sides of the lower abdomen.

24. Inguinal hernias are by far the most common type of hernia, representing approximately two-thirds of adult hernias and are far more common in men than women. They occur in about 15% of the adult population and inguinal hernia repair is one of the most commonly performed surgical procedures in the world.

25. Inguinal hernias occur in a part of the abdominal wall called the “inguinal canal” where a man’s testicles descend before birth. This leaves a natural weak spot called the internal inguinal ring that can eventually develop into a hernia if it doesn’t seal properly.

26. Inguinal hernias can be classified as either direct or indirect. An indirect inguinal hernia occurs through the natural weakness in the internal inguinal ring. A direct inguinal hernia is a

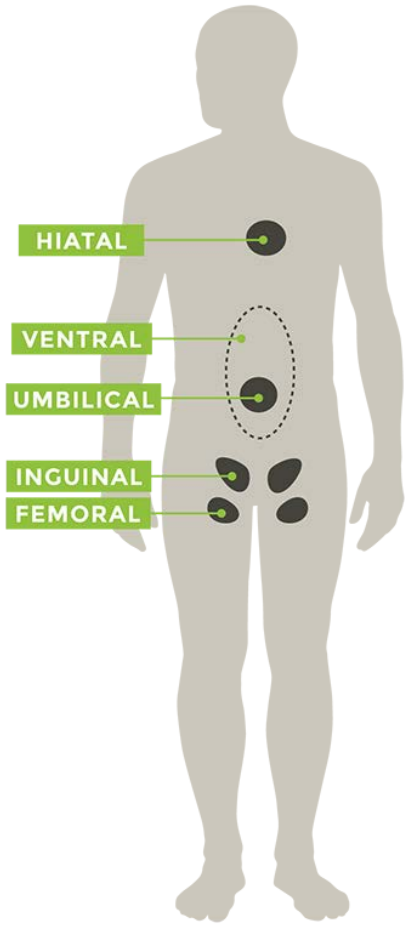
result of weakness in the floor of the inguinal canal and is more likely to develop in older men over the age of 40. The floor of the inguinal canal is located just below the internal inguinal ring.

27. A ventral hernia is a sac or pouch that forms from the inner lining of the abdomen that pushes abdominal content such as bowel through a hole in the abdominal wall. Umbilical hernias are a type of ventral hernia that occurs around the bellybutton.

28. An incisional hernia is a type of hernia caused by an incompletely-healed surgical wound. Incisional hernias are often ventral. It is estimated that 1 in 4 men and 1 in 50 women will require surgery for an incisional hernia during their lifetime.

29. A femoral hernia occurs in the upper part of the thigh near the groin where there is a natural space called the “femoral canal” where intestines can protrude. Femoral hernias are more common in women than men as they are usually the result of pregnancy and childbirth.

30. A hiatal hernia occurs when a portion of the stomach protrudes up through the diaphragm into the chest. It is most common in persons over the age of 50. Hiatal hernias are often accompanied with gastrointestinal reflux, a burning sensation which results when the stomach contents leak upwards into the esophagus.



31. Once hernias are caused, they may or may not present pain. The main symptom of a hernia is a bulge or swelling in the groin, abdomen, or scrotum that often feels like a round lump.

32. If left unattended, the weak spot can grow and simple acts like sneezing, coughing, laughing, bending over, or lifting heavy objects can be very painful.

II. Hernia Repair

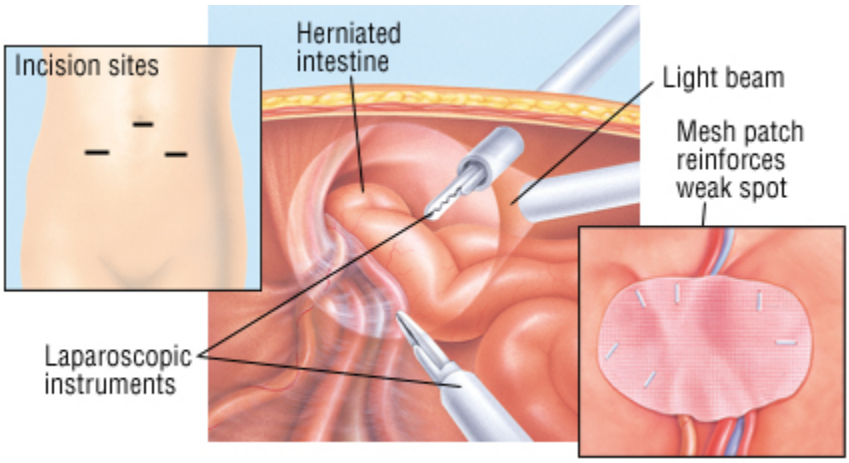
33. Hernia repair can be achieved through several methods, including, but not limited to: (i) herniotomy, (ii) herniorrhaphy, and (iii) hernioplasty. Herniotomy is the removal of the hernial sac only – this is generally not adequate for adults as it only addresses the symptom and not the

problem making it likely that the hernia would reoccur quite quickly. Herniorrhaphy is a herniotomy with a repair of the posterior muscle tissue – this is generally adequate only for a small hernia in a young adult with good musculature. Hernioplasty is a herniotomy and reinforcement of the muscle tissue with a synthetic mesh (the subject of the present Statement of Claim).

34. Until 1958, abdominal wall hernias were closed with primary suture repair. In 1958, Dr. Francis Usher published his technique using a polypropylene mesh. This led to the Lichtenstein repair some 30 years later which popularised mesh for hernia repair. Currently, about one million meshes are used per year world-wide.

35. There are two types of surgeries for hernias – open and laparoscopic repairs. Laparoscopic hernia repair is similar to other laparoscopic procedures[4] and it is referred to as "minimally invasive surgery". General anesthesia is given, and a small cut (incision) is made in the skin near the bulge. The abdomen is then inflated with gas so that the surgeon can see the abdominal organs with a laparoscope (a telescope-like instrument with a camera on the end. Laparoscopic repairs are possible with surgical experts, but the learning curve is quite long (200-250 cases) and the severity of complications is greater.

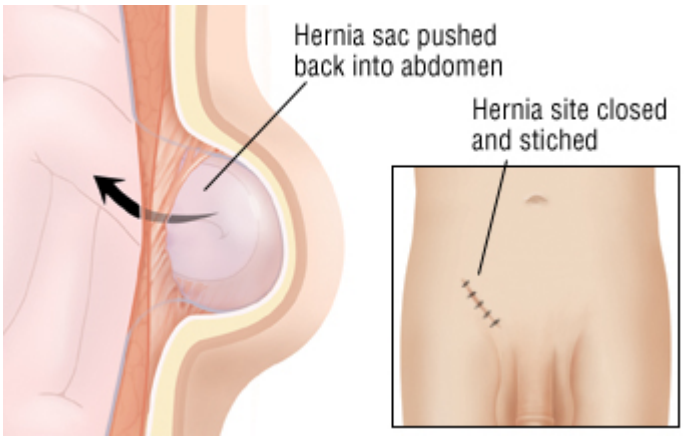
[4] Laparoscopy is a surgery that uses a thin, lighted tube put through a cut (incision) in the belly to look at the abdominal organs or the female pelvic organs.



36. The majority of hernia repair surgeries today are performed laparoscopically and the Hernia Mesh Device is placed deeper into the abdominal cavity (intraperitoneally as opposed to preperitoneally[5]), meaning that the Hernia Mesh Device is placed directly on the organ, which increases the risk of adhesion thereto.

37. By contrast, the traditional open hernia repair surgery involves a single, several inch-long incision. If the hernia is bulging out of the abdominal wall (a direct hernia), the bulge is pushed back into place. If the hernia is going down the inguinal canal (indirect), the hernia sac is either pushed back or tied off and removed.

[5] The peritoneum is the membrane that forms the lining of the abdominal cavity – the intraperitoneal space is located within the abdominal cavity, but wrapped in peritoneum. The stomach and the intestines as intraperitoneal.



38. Depending on the surgeon and on the surgery itself, the Hernia Mesh Device may be placed in: (i) an "overlay" position – i.e. between the skin/subcutaneous tissue and the rectus abdominis. Mesh is easiest to remove when it is placed in the overlay position, (ii) an "inlay" position – i.e. between layers of the rectus abdominis, or (iii) an "underlay" position – i.e. between the rectus abdominis and the peritoneum. The hernia mesh has a higher chance of attaching to the patients underlying organs when placed in the underlay position.

39. Hernias have a high rate of recurrence and surgeons often use surgical mesh to strengthen the area and to reduce the chances of it reoccurring. Since the 1980s, there has been an increase in mesh-based hernia repair surgery – by 2000, non-mesh repairs represented less than 10% of groin hernia repair techniques.

III. What is "Mesh" and What are the Hernia Mesh Devices?

40. In general, surgical mesh is a loosely woven sheet which is used as either a permanent or temporary support for organs and other tissues during surgery. Surgical mesh is created from both inorganic and biological materials and is used in a variety of surgeries.

41. In terms of hernia repair surgery, there are many types of mesh products available. The mesh can be in the form of a patch that goes either under or over the weak area or it can be in the form of a plug that goes inside the hole.

42. The Hernia Mesh Devices at issue in the present Application are both coated and uncoated. The uncoated mesh examples are: (i) the Kugel Hernia Mesh Patch, (ii) the 3DMax Mesh, and (iii) the PerFix Plug and the coated mesh examples are: (iv) the Ventralex ST Hernia Mesh, and (v) the Sepramesh IP Composite, all of which are made out of polypropylene, a synthetic plastic-like material that shrinks, erodes, and degrades over time.

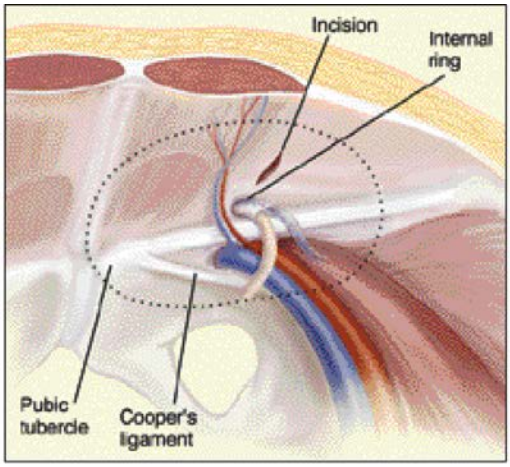
43. Due to the complications that polypropylene was causing when it came in direct contact with the human tissue, the demand for a coated (composite) hernia mesh skyrocketed. Any company with a composite mesh to sell could rapidly increase its nationwide market share. Mesh products were already one of the most profitable medical devices a company could manufacture, many making over $100,000,000 a year, but a composite mesh also sells for approximately 15–20 times more than an uncoated polypropylene mesh.

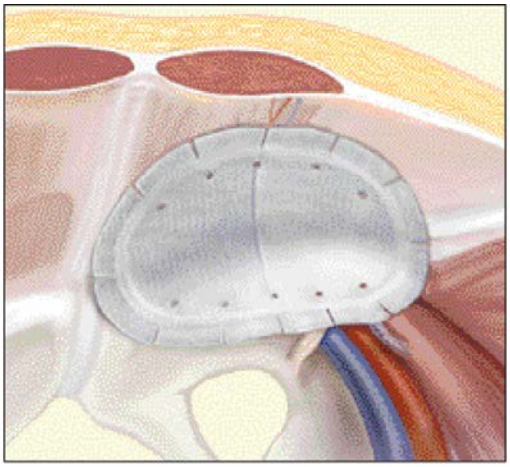
44. It is in this sense that the coated polypropylene mesh is a band-aid solution that caused an even bigger problem as it meant that patients were now being implanted with cheap plastic that degrades with highly allergenic properties on it.

45. Thus, the Defendants rushed to get a composite mesh on the market.

i) <u>The Kugel Hernia Mesh Patch</u>

46. The Kugel Mesh Patch is constructed of a double layer of monofilament polypropylene with a ring in the middle of the mesh to help it to maintain its shape. The ring is designed with "memory recoil" to allow for the patch to be folded, inserted through a small abdominal incision and, once in place, to spring open and lie flat over the affected area.





47. The Kugel Hernia Patch is marketed by the Defendants as an "Open Posterior Approach to a Preperitoneal Inguinal Repair".

48. Unfortunately, the ring was susceptible to buckling or breakage, causing a number of painful, life-threatening and potentially fatal complications.

49. The main issue with the Kugel hernia mesh is that it is made of polypropylene, which shrinks and degrades over time. As the polypropylene mesh shrinks, more and more force is applied to the ring. Eventually, the ring breaks due to the shrinkage of the polypropylene.

50. The Kugel Hernia Mesh Patches were one of first and are the most well-known hernia meshes to be recalled. In the United States, Defendant C.R. Bard recalled several lots of the Kugel hernia patches in 2005, 2006, and 2007.

51. In Canada, on January 9, 2006, Health Canada recalled only the Bard Composix Kugel Mesh X-Large Patch for the following reason.

> "Davol as [sic] received complaint records of the PET recoil ring breaking, which could potentially lead to bowel perforation and or chronic enteric fistulas."

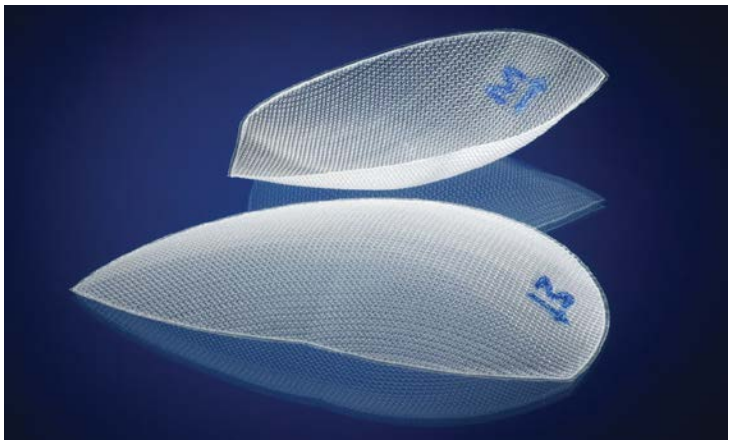
52. In the United States, multiple lots of the Kugel Hernia Mesh Patches were recalled due to a large number of reported ring breaks. Many patients have suffered bowel perforations as a result of the inner ring of the Kugel Hernia Mesh Patches breaking.

53. To date, only one sizing of the Kugel Hernia Mesh Patch has been recalled in Canada despite the composition of all sizes being identical. The Defendants have only recalled this one

product in Canada and only limited lots in the U.S. of the Kugel Hernia Mesh Patch, claiming that only certain lots had defective rings. The Defendants continue to develop, design, manufacture, produce, supply, market, label, package, promote, advertise, import, distribute, and/or sell the Kugel Hernia Mesh Patches at present.

ii) The 3DMax Mesh

54. The 3DMax Mesh is constructed of knitted polypropylene and is used to treat inguinal hernias. It has a three-dimensional design and is in an anatomically-curved shape.



55. The 3DMax Mesh is marketed by the Defendants as "A clinically proven fixation-free product for laparoscopic approaches such as TAPP, TEP, and Robotic TAPP"[6] and the Defendants claim that the "3DMAX mesh has been designed based on careful and precise anatomical research of the inguinal anatomy".

56. The main issue with the 3DMax Mesh is that it is made of polypropylene, which shrinks and degrades over time. When the 3DMax Mesh shrinks, it commonly folds on top of itself due to its curved design. In addition, to the shrinkage, the degradation of the polypropylene involves cracking and pieces breaking off.

[6] TAPP (transabdominal extraperitoneal) and TEP (total extraperitoneal).

57. Polypropylene can erode through soft tissue and cause damage to nearby nerves. If the polypropylene erodes through enough tissue, it will attach to the spermatic cord in men. A highly skilled surgeon can carefully dissect the 3DMax from the spermatic cord if it is treated early enough. Eventually, the 3DMax max will erode into and through the spermatic cord. If the damage to the spermatic cord is too great, the testicle will also have to be removed. The pain caused by the 3DMax is so severe and debilitating that thousands of men have opted to have their testicle removed to alleviate the pain.

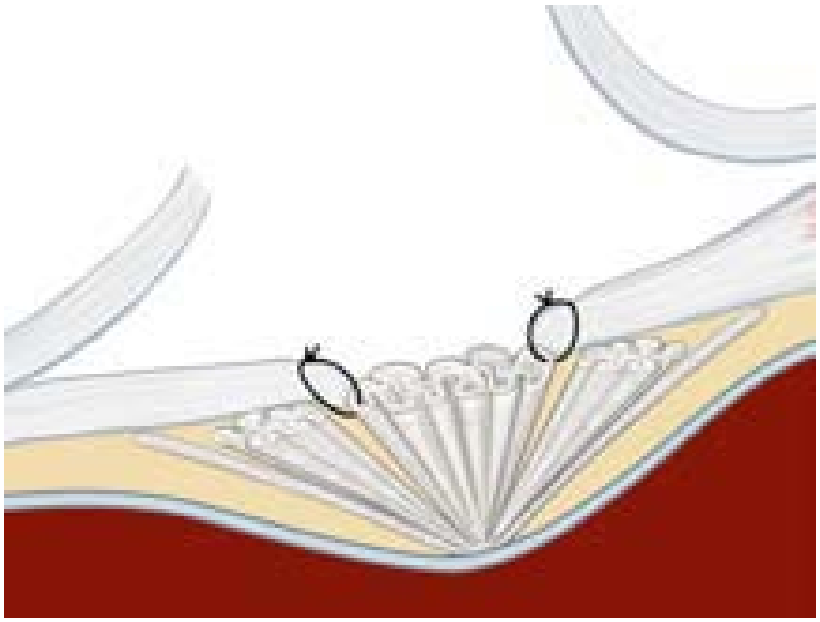
58. The 3DMax Mesh has caused thousands to suffer chronic, debilitating pain. Men are frequently reporting sexual dysfunction associated with the 3DMax Mesh.

59. To date, the 3DMax Mesh has not been recalled in Canada despite its danger to human health and safety. The Defendants continue to develop, design, manufacture, produce, supply, market, label, package, promote, advertise, import, distribute, and/or sell the 3DMax Mesh at present.

iii) The PerFix Plug

60. The PerFix Plug is another woven polypropylene mesh used to treat inguinal hernias. It is designed with pleated edges to conform to defects of various sizes and shapes.


DAVOL
Contents: 1
REF 0112760
Bard® Mesh
PerFix® Plug, Medium
Monofilament Knitted Polypropylene



61. The PerFix Plug is marketed by the Defendants as "A quick and simple preperitoneal underlay Modified Technique for the repair of groin hernias" and they represented that there was a "low complication rate – 0 mesh infections or mesh migration".

62. In addition to the major issue of it being made out of polypropylene, which shrinks and degrades over time, the woven design of the PerFix Plug creates small pores (holes) throughout the mesh. Nerves grow into these pores and attach to the mesh soon after implant. As the mesh erodes and moves through the inguinal canal, it pulls and stretches the nerves attached to it. The nerve stretching causes debilitating pain.

63. Unfortunately, the pain caused from nerve stretching is essentially untreatable and not even opioids are effective at treating this nerve pain.

64. In addition, the PerFix plug has been observed to become unwoven over time. In many cases, the patient's body rejects small pieces of the unwoven PerFix Plug. This rejection process is slow and results in a chronic non-healing wound, which oftentimes leads to infections.

65. Like the 3DMax Mesh, the PerFix Plug must be removed before it erodes into the spermatic cord in men. Once the PerFix Plug has eroded into the spermatic cord, it could become impossible to remove without also removing a testicle.

66. Many men are reporting severe, chronic groin and leg pain after being implanted with the PerFix Plug. The pain is so debilitating that numerous men report being unable to work or even walk.

67. To date, the PerFix Plug has not been recalled in Canada despite its danger to human health and safety. The Defendants continue to develop, design, manufacture, produce, supply, market, label, package, promote, advertise, import, distribute, and/or sell the PerFix Plug at present

iv) The Ventralex Hernia Mesh Patch and the Ventralex ST Hernia Mesh Patch

68. The Ventralex ST Hernia Mesh Patch is a monofilament polypropylene mesh with a "bioresorbable coating", which is meant to be placed against the bowels or the sensitive organs to prevent adhesion formation with the polypropylene mesh itself – while the Ventralex Hernia Mesh Patch is not coated.

69. The Ventralex ST Hernia Mesh Patch is marketed by the Defendants as "Efficient, Easy, Proven".

70. In addition to the major issue of it being made out of polypropylene (as are the rest of the Hernia Mesh Devices), which shrinks and degrades over time, the "bioresorbable coating" causes severe inflammatory and autoimmune reactions in humans.

71. The Defendants promote the mesh coating as a "barrier" and instruct surgeons to use the coating as such. The U.S. FDA requires any "barrier" type of medical device to undergo pre-market approval and pre-clinical studies to ensure the device's safety. Instead of conducting safety studies, the Defendants simply informed the U.S. FDA that they would not promote their hernia mesh as a "barrier" medical device.

72. The Defendants based the design of the Ventralex ST Hernia Mesh Patch off of a prior Hernia Mesh Device design, the Kugel Hernia Mesh Patch (see section (i) above).

73. The Defendants recalled several lots of the Kugel Hernia Mesh Patches approximately a decade ago in the U.S. and Health Canada made one recall in Canada in 2006.

74. Patients are having severe inflammatory and autoimmune reactions to the Ventralex ST Patch.

75. To date, neither the Ventralex Mesh Patches nor the Ventralex ST Mesh Patches have been recalled in Canada (or in the U.S.) despite their danger to human health and safety. The Defendants continue to develop, design, manufacture, produce, supply, market, label, package, promote, advertise, import, distribute, and/or sell the Ventralex ST Mesh Patches at present.

v) <u>The Sepramesh IP Composite</u>

76. The Sepramesh IP Composite is a polypropylene mesh with an absorbable hydrogel coating on one side, which is meant to be resorbed by the body within 30 days. The Sepramesh is intended to "Separate" the polypropylene from the bowel.

77. The SepraMesh is designed with a bioresorbable lipid coating that incites high levels of inflammation once implanted in the human body. Chronic inflammation caused by the SepraMesh leads to slow wound healing and chronic infection.

78. The SepraMesh is marketed by the Defendants as having "The strength of a permanent mesh with the effectiveness of a bioresorbable coating" and that it is "Built on the foundation of Sepra technology, with over 13 years of proven clinical success".

79. The Sepramesh is built on "2 key components: sodium hyaluronate (HA) and carboxymethylcellulose (CMC)"; the same as the Seprafilm products.

80. On December 20, 2013, Defendant Genzyme Corporation agreed to pay $22.28 million to resolve allegations that it "marketed, and caused false claims to be submitted to federal and state health care programs for use of, a 'slurry' version of its Seprafilm adhesion barrier". The U.S. Department of Justice stated the following:

> "There will be consequences when medical device companies alter products to increase sales and profits without regard for risks to patient safety…Federal health care participants should receive only devices that are medically reasonable and necessary."

81. On September 3, 2015, Defendant Genzyme Corporation agreed to resolve criminal charge that it violated the U.S. Food, Drug and Cosmetic Act (U.S. FDCA) with regard to the unlawful distribution of Seprafilm, a surgical device that it marketed and promoted by paying a sum of $32,587,439.

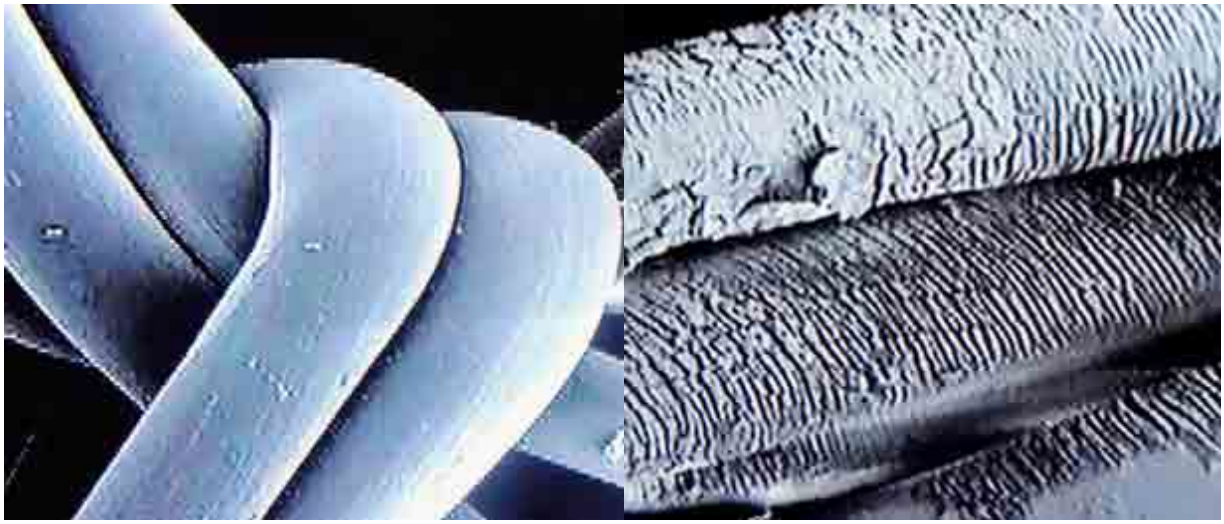
82. To date, the SepraMesh has not been recalled in Canada (or in the U.S.) despite its danger to human health and safety. The Defendants continue to develop, design, manufacture, produce, supply, market, label, package, promote, advertise, import, distribute, and/or sell the SepraMesh at present.

IV. Polypropylene – the Common Denominator

83. Polypropylene (PP), also known as polypropene, is a thermoplastic polymer used in a wide variety of applications including packaging and labeling, textiles (e.g., ropes, thermal underwear and carpets), stationery, plastic parts and reusable containers of various types, laboratory

equipment, loudspeakers, automotive components, and polymer banknotes. As has been seen above, the Defendants used this material in their design of the Hernia Mesh Devices.

84. Polypropylene is a cheap plastic. Once implanted, polypropylene begins to degrade. As polypropylene degrades it cracks, pieces break off, and it starts to shrink. Polypropylene can also erode through soft tissue and damage nearby nerves. If the polypropylene erodes through enough tissue it causes serious damages and may necessitate the removal of the tissue itself.



Polypropylene before implantation Polypropylene 18 months after implantation

85. The Material Data Safety Sheet (MSDS) for Polypropylene states the following prohibited use: “Applications involving permanent implantation into the body”.

86. The scientific evidence (as will be discussed hereinbelow) indicates that the polypropylene material from which the Hernia Mesh Devices are made is biologically incompatible with human tissue and promotes a negative immune response in a large number of the population implanted with the Hernia Mesh Devices.

87. The Defendants have a long history of creating the Hernia Mesh Devices out of polypropylene. They have already faced thousands of lawsuits in the U.S. and class proceedings in Canada over their transvaginal mesh and bladder sling products, which are also made from polypropylene. Despite the known risk associated with polypropylene, the Defendants continue to design, manufacture, and produce the Hernia Mesh Devices with it.

V. The Scientific Studies

88. The medical and scientific literature studying the effects of polypropylene mesh, like that of the Hernia Mesh Devices at issue herein, has examined each of these injuries, conditions, and complications, and has reported that they are causally related to the Hernia Mesh Devices.

89. There have been many publications of peer-reviewed studies documenting the perilous safety shortcomings of the Hernia Mesh Devices; any one of which should have prompted the Defendants to redesign or to discontinue their products. Instead, those criticisms only caused Defendants to amplify their efforts to champion their product.

90. However, the Defendants funded studies to demonstrate that there was a lower rate of hernia recurrence when hernia mesh was utilized. These studies were lacking in many ways, such as the length of time that patients were monitored after mesh implantation and what were considered "normal complications." Hernia recurrences and complications that happen 10 years later aren't captured by the studies.

91. The various studies and publications constituted a clear indication that Hernia Mesh Devices were defective in that they have the potential to causes serious complications whereas

other alternate methods were safer. These publications include, but are not limited to, the following:

a) R. Gonzalez et al. “Resistance to adhesion formation: A comparative study of treated and untreated mesh products placed in the abdominal cavity” (2004) 8 Hernia 213-219;

b) J.W.A. Burger et al., “Evaluation of new prosthetic meshes for ventral hernia repair” (2006) 20 Surg Endosc 1320-1325;

c) J. Jonas, “The Problem of Mesh Shrinkage in Laparoscopic Incisional Hernia Repair” (2009) 134:3 Zentralbl Chir. 209-13 (abstract only as it is in German);

d) F. E. Muysoms, J. Bontinck, & P. Pletinckx, “Complications of mesh devices for intraperitoneal umbilical hernia repair: a word of caution” (2011) 15 Hernia 463-468;

e) Corey R. Deeken, Keith M. Faucher, & Brent D. Matthews, “A review of the composition, characteristics, and effectiveness of barrier mesh prostheses utilized for laparoscopic ventral hernia repair” (2012) 26 Surg Endosc 566-575;

f) M. Ditzel et al., “Biologic meshes are not superior to synthetic meshes in ventral hernia repair: an experimental study with long-term follow-up evaluation” (2013) 27 Surg Endosc 3654-3662;

g) Marc H. F. Schreinemacher et al., “Coated meshes for hernia repair provide comparable intraperitoneal adhesion prevention” (2013) 27 Surg Endosc 4202-4209;

h) Mylan T. Nguyen, MS et al., “Comparison of Outcomes of SyntheticMesh vs Suture Repair of Elective Primary Ventral Herniorrhaphy – A Systematic Review and Meta-analysis” (2014) 149:5 Jama Surg. 415-421;

i) Robert Bendavid et al., “Mesh-Related SIN Syndrome. A Surreptitious Irreversible Neuralgia and Its Morphologic Background in the Etiology of Post-Herniorrhaphy Pain” (2014) 5 International Journal of Clinical Medicine 799-810;

j) Vladimir V. Iakovlev, Scott A. Guelcher, & Robert Bendavid, “Degradation of polypropylene in vivo: A microscopic analysis of meshes explanted from patients” (2015) wileyonlinelibrary;

k) R.B. Baucom et al., “Evaluation of long-term surgical site occurrences in ventral hernia repair: implications of preoperative site independent MRSA infection » (2016) 20 Hernia 701-710;

l) Odd Langbach et al., “Oral, intestinal, and skin bacteria in ventral hernia mesh implants” (2016) 8 Journal of Oral Microbiology 31854.

92. The 2004 Gonzalez et al. study, in testing the new materials that were devised to prevent postoperative adhesions when placing a prosthesis in contact with abdominal contents, found that “The incidence of adhesions and work and strength of adhesion separation are reduced when using a treated mesh, compared to the untreated mesh and the control group without mesh”. Thus, it was found that the resorbable coating is good in terms of preventing contact between the polypropylene and the human body; however, the study did not test the human body’s reaction to the substance itself.

93. The 2006 J.W.A. Burger et al. study, in the testing of the amount of adhesion formation with a coated mesh as opposed to an uncoated mesh, concluded that it was preferable to have a coated mesh to an uncoated mesh in terms of adhesion formation.

94. The 2009 German Jonas J study, in an overview of published studies on the incidences of polypropylene shrinkage found that “Eleven experimental and 3 clinical studies published data referring to shrinkage of intraperitoneally placed meshes. Polypropylene meshes showed shrinkage in the order of 3.6-25.4 %, PTFE meshes 4.0-51.0 %, coated polypropylene and polyester meshes 6.1-33.6 %”. Thus, the shrinkage is quite significant, particularly so when you take into account

the fact that human tissue is involved. During laparoscopic hernia repair, the surface area of the abdominal wall is stretching by about 80% and this must be accounted for. Coated polypropylene meshes tend to shrink more than the uncoated ones; however, the coated meshes as we have seen tend to form less adhesions;

95. The 2011 F.E. Muysoms et al. study, in testing the safety of dual layer meshes (such as the Kugel Hernia Mesh Patch) determined that it was preferable to place them preperitoneally than intraperitoneally. The study determined that there is a need for a better identification, classification and reporting system for hernia mesh infections, stating the following:

> "There is a complete lack of convincing data on these mesh devices in the medical literature. No long-term data have been published, and, for three of the four mesh devices available, no publications on their use in humans were found. We think that surgeons adopting innovative mesh devices should register and follow their patients prospectively, at least until there are enough published studies with sufficiently large patient samples, acceptable follow up times, and favourable outcomes.
> …
> We think that mesh devices should be used to repair small ventral hernias only when patients are entered in a prospective registry and follow up program or in clinical trials, at least until studies are published with a sufficient sample of patients, an acceptable follow up time, and favourable outcomes."

96. The 2012 Corey R. Deeken et al. study, in testing the characteristics and effectiveness of eight different coated meshes, both permanent and absorbable, concluded that polypropylene is "unsuitable for intra-abdominal placement because of its tendency to induce bowel adhesions" stating the following:

> "It is likely that the components of these barriers incite a wide range of inflammatory responses resulting in the range of adhesion coverage and tenacity observed in the preclinical and clinical studies reviewed. Clinical trials are needed to more appropriately define the clinical effectiveness of these barriers."

97. The 2013 M. Ditzel et al. study, in testing adhesion formation, shrinkage, incorporation and histologic characteristics with uncoated meshes for 5 different brands, noted that “In laparoscopic incisional hernia repair, direct contact between the prosthesis and the abdominal viscera is inevitable, which may lead to an inflammatory reaction resulting in abdominal adhesion formation.” The authors advise additional research is necessary, and to be wary of short-term experimental results on laparoscopically placed hernia mesh. The study also concluded that “significant changes that take place between 30 and 90 days should lead to careful interpretation of short-term experimental results”.

98. The 2013 March H.F. Schreinemacher et al. study, in testing the efficacy of coated meshes as compared to uncoated meshes when place intraperitoneally, concluded that the coating reduces adhesion formation and that the physical presence of most anything to block the body’s contact with the mesh is preferable to none.

99. The 2014 Mylan T. Nguyen study, in conducting a systematic review and meta-analysis of the occurrence of hernia recurrence, surgical site infections (SSI), and seromas in terms of suture repair verses mesh repair, concluded that “mesh repair has a small reduction in recurrence rates compared with suture repairs for primary ventral hernias, but an increased risk of seroma and SSI were observed. Further high-quality studies are necessary to determine whether suture or mesh repair leads to improved outcomes for primary ventral hernias.” Thus, Hernia mesh repair was associated with a slightly lower rate of recurrence, but a higher rate of severe complications.

100. The 2014 Robert Bendavid et al. study, in testing the occurrence of Surreptitious Irreversible Neuralgia (SIN) caused by the insertion of synthetic mesh, observed that “All of the explanted meshes had nerves within the scar tissue encasing the mesh (interstitial infiltration).

Nerve ingrowth through the pores of the mesh (micro-entrapment) was detected in 90% of the explanted mesh specimens. Additionally, nerves were detected entrapped within the folds and deformations of mesh explants. Ingrown vessels showed congestion and focal fibrin thrombi". It was concluded that nerves are in a vulnerable position when exposed to the nesh and while within its pores.

101. The 2015 Vladimir V. Iakovlev et al. study, in testing whether polypropylene degrades inside the body, concluded that there were several features of the specimens that indicated degradation: "inflammatory cells trapped within fissures, melting caused by cautery of excision surgery, and gradual but progressive growth of the degradation layer while in the body. Cracking of the degraded material indicated a contribution to clinically important mesh stiffening and deformation. Chemical products of degradation need to be analyzed and studied for their role in the mesh-body interactions".

102. The 2016 R.B. Baucom study, in testing the infection rate following a ventral hernia repair over 2 years (and not the short time period that other studies had been testing), found that 31% experienced complications within 2 years including cellulitis, necrosis, nonhealing wound, seroma, hematoma, dehiscence, and fistula. It concluded, based on the significant incidence thereof, that it is important to evaluate the long-term effects of hernia repair surgery.

103. The 2016 Odd Langbach et al. study tested bacterial colonization of mesh implants in patients with failed hernia meshes who were not exhibiting clinical signs of infection. All participants were found to have gingivitis and 33% had infected gums and teeth. Oral bacteria was discovered on 43% of explanted hernia mesh. The study discusses the difficulty in knowing the real rate of hernia mesh infections, due to lack of standardized criteria to define infection, lack of

follow-up exams, and lack of intervention when complications arise. It notes that hernia mesh infection is the most common reason for mesh removal.

104. As the studies confirm, the Hernia Mesh Devices pose serious health risks when surgically implanted in patients, which wholly negate its positive elements of hernia repair.

105. Despite these studies, the Defendants have not done anything to alter the design of the Hernia Mesh Devices, nor have they made any efforts to warn physicians or the public about these risks. To do so would be against their economic interests.

VI. The Defendants' Marketing Practices

106. Despite the risks of serious adverse events, the Defendants aggressively promoted the Hernia Mesh Devices.

107. The Defendants made public statements in the form of written product descriptions, product labels, promotional materials and other materials that asserted that implanting the Hernia Mesh Devices in patients was safe and would not cause harm. These statements were made with the intent that medical professionals and members of the public would rely upon them so that the Hernia Mesh Devices would be implanted in patients. When the Defendants made these statements, they knew or should have known that the they were false and/or inaccurate.

108. Representatives of the Defendants also made statements to numerous individuals, including but not limited to medical professionals, that implanting the Hernia Mesh Devices in patients was safe and would not cause harm. When the Defendants' representatives made these statements, they knew or should have known that they were false and/or inaccurate.

109. The Defendants knowingly and deliberately made material misrepresentations or did not disclose information to Health Canada concerning the design, manufacture, safety, efficacy, and risks of the Hernia Mesh Devices.

110. The Defendants have invested millions of dollars in teams of sales representatives who visit and contact members of the medical community, including doctors, purporting to "educate" them about the Hernia Mesh Devices. These sales representatives have not notified patients, the medical community, or hospitals that the Hernia Mesh Devices can cause the Hernia Mesh Injuries and/or the Dangerous Complications.

111. The serious side effects of the Hernia Mesh Devices rendered their design defective, which was a significant factor in causing the Plaintiff's and Class Members' injuries.

112. The Defendants' marketing of the Hernia Mesh Devices continues to fail to adequately warn consumers, healthcare professionals and the public of the serious risk of experiencing the Hernia Mesh Injuries and/or Dangerous Complications.

113. The Hernia Mesh Devices have been, and continue to be marketed to the medical community and to patients as a safe, effective, reliable, medical device, implanted by safe and effective, minimally invasive surgical techniques, and as safer and more effective as compared to other available feasible alternative treatments for hernias, and competing medical devices.

114. These misrepresentations had the effect of misleading healthcare providers about the safety of the Hernia Mesh Devices for surgical implantation.

115. Physicians relied upon the above representations and advertisements to the Plaintiff's and Class Members' detriment. A reasonably prudent physician would not surgically implant the Hernia Mesh Devices into a human being if s/he was fully apprised of the dangers and risks associated with doing so. However, through misrepresentations to the public, the medical community, and Health Canada, the Defendants actively concealed the Dangerous Complications of the Hernia Mesh Devices.

116. The Plaintiff and his physician(s) were therefore unaware of the Dangerous Complications associated with the Hernia Mesh Devices.

VII. Safe Alternatives to the Hernia Mesh Device Repairs

117. There are many feasible alternatives to the Hernia Mesh Devices in the form of non-polypropylene hernia mesh products or other surgical and non-surgical alternatives which do not cause the Hernia Mesh Injuries such as:

a) The Shouldice Repair: A two-layer suture-only hernia repair utilizing the patient's fascia and tendon,

b) The McVay (Cooper's Ligament) Repair: Abdominal tendons are sutured to the inguinal ligament,

c) The Bassini Repair: A suture inguinal hernia repair that preserves the spermatic cord,

d) The Desarda Repair: A suture only repair using multiple layers of fascia,

e) The Darn Repair: A suture-only repair between the conjoined tendon and the inguinal ligament without approximating the two structures, and/or

f) The Wait-and-See Approach (depending on the severity of the hernia and/or the pain related thereto).

118. Long before mesh was utilized to repair hernias, surgeons used the Shouldice Hernia Repair. The Shouldice Hernia Repair technique originated (and got its name) from the Shouldice Hospital in Ontario where the technique is still favoured to this day. It is internationally recognized as one of the safest and most effective techniques for repairing hernias. When performed by a specially trained and well-experienced Shouldice surgeon, this pure, natural tissue repair virtually eliminates complications or repeat hernias (recurrences).

119. For over 70 years, the Shouldice Hospital has maintained a success rate of 99.5% on primary inguinal hernia repairs.

120. Because the muscles and connective tissue of the abdominal wall are arranged in three separate layers, prior to repairing any weaknesses, the fatty tissues and any part of the intestine (bowel) that may have bulged through the abdominal wall back are placed back inside the abdomen where they belong. Then, the surgeon repairs each muscle layer individually, using a technique that puts no tension on the natural tissue. By carefully overlapping and securing each layer, they strengthen and reinforce this section of the abdominal wall.

121. As part of the Shouldice procedure, the surgeon will also perform a thorough search for other hernias in the area and repair them as well. Research has shown that up to 13% of people with hernias have a second weak spot in their muscles or a ’hidden’ hernia.

122. In most cases, general anesthesia is not even necessary to perform the Shouldice Hernia Repair. Typically, a local anaesthetic, a sedative (sleeping pill) and an analgesic (pain pill), is all

that is required. Not having to rely on general anesthesia greatly reduces surgical complications, improves recovery, and increases comfort levels.

123. The McVay Repair involves the suture (stitching) of the conjoined (transversus abdominis and internal oblique) tendon to the inguinal ligament with interrupted nonabsorbable sutures.

124. The Bassini Repair involves the suturing the transversalis fascia and the conjoined tendon to the inguinal ligament behind the spermatic cord, as well as placing a vertical relaxing incision in the anterior rectus sheath.

125. The Desarda technique, presented in 2001, is an original hernia repair method using an undetached strip of external oblique aponeurosis[7]. The beneficial results of this technique are substantially similar to that of using a mesh, but without the Hernia Mesh Injuries.

126. The Darn Repair is a pure tissue tensionless technique that is performed by placing a continuous suture between the conjoined tendon and the inguinal ligament without approximating the two structures.

127. If the hernia is not causing pain or discomfort, doctors may recommend a Wait-and-See approach with monitoring to see if the condition worsens – where there is no pain and no symptoms, sometimes it is simply best to just wait-and-see.

128. Small hernias can easily be repaired with sutures by an experienced surgeon. The difficulty with hernias is they are very difficult to permanently repair. There is a high rate of hernia

[7] Aponeurosis is a sheet of pearly-white fibrous tissue that takes the place of a tendon in sheet like muscles having a wide area of attachment.

recurrence, both with sutures and with mesh. When sutures fail and the hernia comes back, the surgeon can usually try to stitch the hernia back up. When a mesh fails and the hernia comes back, many severe complications can occur. Also, the hernia is usually much larger after mesh failure. Abdominal tissue and muscle typically adheres to the mesh and must be removed along with it.

VIII. The Product Defects

129. The Hernia Mesh Devices have numerous defects that create unreasonable risks of injuries and side effects with permanent adverse health consequences, which include, but are not limited to, the following:

a) The use of polypropylene material in the Hernia Mesh Devices and the immune reaction that results from such material, causing adverse reactions and injuries,

b) The design of the Hernia Mesh Devices to be inserted into and through an area of the body with high levels of bacteria that can adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries,

c) Biomechanical issues with the design of the Hernia Mesh Devices, including, but not limited to, the propensity of the Hernia Mesh Devices to contract or shrink inside the body, that in turn causes surrounding tissue to be inflamed, become fibrotic[8], and contract, resulting in injury,

d) The Hernia Mesh Devices and their mesh material migrate from the location of their implantation, adversely affecting tissue and patient health,

e) The Hernia Mesh Devices and the mesh material erode into surrounding tissue and organs, adversely affecting tissue and patient health,

[8] The formation of an abnormal amount of fibrous tissue in an organ or part as the result of inflammation, irritation, or healing.

f) Adverse reactions to the mesh, adhesions, injuries to nearby organs, nerves or blood vessels, and complications including infection, chronic pain, and hernia recurrence,

g) The propensity of the Hernia Mesh Devices to “creep”, or to gradually elongate and deform when subject to prolonged tension inside the body,

h) The inelasticity of the Hernia Mesh Devices, causing them to be improperly mated to where they are implanted, and causing pain during normal daily activities,

i) The propensity of the Hernia Mesh Devices for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, react with human tissues, and results in continuing injury over time,

j) The Hernia Mesh Devices regularly fail to perform the purpose of their implantation such that the patient requires additional repair, removal of the device, and/or replacement of the device, all involving repeated treatment and surgery,

k) The Hernia Mesh Devices provoke a foreign-body response, become embedded in human tissue over time, such that if they need to be removed due to its various defects, complete removal is difficult or impossible, the removal poses significant risk of damage to organs, nerves and tissues, and results in additional scar tissue, adversely affecting patient health,

l) The Hernia Mesh Devices cause injury resulting in chronic severe debilitating pain, and the pain can persist even after removal,

m) The Hernia Mesh Devices material cause injury resulting in painful sex,

n) The Hernia Mesh Devices are defective in shape, composition, weight, physical, chemical and mechanical properties and are inappropriately engineered for use in the human body, and

o) The risks of the Hernia Mesh Devices do not outweigh their benefits as the risk of recurrence of the hernia is no better than with traditional tissue repairs and/or other hernia repair procedures.

130. The Defendants failed in their duty to adequately warn or instruct Class Members and/or their health care providers of subjects including, but not limited to, the following:

a) The propensity of the Hernia Mesh Devices to contract, retract, and/or shrink inside the body;

b) The propensity of the Hernia Mesh Devices for degradation, fragmentation and/or creep;

c) The inelasticity of the Hernia Mesh Devices, which prevents proper mating with the hernia floor and vaginal region;

d) The rate and manner of mesh erosion or extrusion;

e) The risk of chronic inflammation resulting from the Hernia Mesh Devices;

f) The risk of chronic infections resulting from the Hernia Mesh Devices;

g) The risk of permanent scarring as a result of the Hernia Mesh Devices;

h) The risk of recurrent hernias, intractable hernia pain, and other pain resulting from the Hernia Mesh Devices;

i) The need for corrective or revision surgery to adjust or remove the Hernia Mesh Devices;

j) The severity of complications that could arise as a result of implantation of the Hernia Mesh Devices;

k) The hazards associated with the Hernia Mesh Devices;

l) The Product Defects described herein;

m) Treatment of hernias with the Hernia Mesh Devices is no more effective than feasible available alternatives;

n) Treatment of hernias with the Hernia Mesh Devices exposes patients to greater risk than feasible available alternatives;

o) Treatment of hernias with the Hernia Mesh Devices makes future surgical repair more difficult than feasible available alternatives;

p) Use of the Hernia Mesh Devices puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q) Removal of the Hernia Mesh Devices due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r) Complete removal of the Hernia Mesh Devices may not be possible and may not result in complete resolution of the complications, including pain.

IX. The Defendants' Liability

131. Despite the vast amount of evidence that the Hernia Mesh Devices cause the Hernia Mesh Injuries, the Defendants have either failed to investigate or conduct any studies on the serious side effects of the Hernia Mesh Devices and/or failed to make public the results of any studies or investigations that they might have conducted.

132. A reasonably prudent medical device researcher, developer, designer, manufacturer, tester, producer, supplier, marketer, labeller, packager, promotor, advertiser, distributer, and/or seller in the Defendants' positions would have adequately warned both doctors and patients of the risks associated with the use of the Hernia Mesh Devices.

133. Despite a clear signal, the Defendants failed to either alert the public and the scientific and medical community or to perform further investigation into the safety of the Hernia Mesh Devices.

134. The Defendants were negligent in the research, development, design, manufacture, testing, production, supply, marketing, labelling, packaging, promotion, advertising, distribution, and/or sale of the Hernia Mesh Devices in one or more of the following respects:

a. They knew or should have known that the surgical implantation of the Hernia Mesh Devices created the risk of the Hernia Mesh Injuries;

b. They failed to ensure that the Hernia Mesh Devices were fit for their intended and/or reasonably foreseeable use and that they were not dangerous to consumers;

c. They failed to conduct proper, adequate, appropriate, and thorough testing to determine whether and to what extent the implantation of the Hernia Mesh Devices poses serious risks, including the Hernia Mesh Injuries;

d. They failed to adequately test the Hernia Mesh Devices to ensure that they were acceptably safe and free from defects prior to releasing them into the Canadian marketplace;

e. They failed to properly, adequately, appropriately, correctly, and timely warn the medical and health community, Health Canada, the Plaintiff, Class Members, and the public in general of the significant and dangerous risks associated with the Hernia Mesh Devices and the severity thereof, both prior to releasing it into the Canadian marketplace and afterward;

f. They failed to use proper care in researching, developing, designing, manufacturing, testing, producing, and supplying their products so as to avoid posing unnecessary health risks;

g. They failed to conduct adequate pre-clinical and clinical testing, post-marketing surveillance and follow-up studies to determine the safety of the medical devices;

h. They failed to advise the medical and scientific communities that the surgical implantation of the Hernia Mesh Devices could result in severe side effects, including but not limited to, the Hernia Mesh Injuries;

i. They misrepresented that the Hernia Mesh Devices were safe and that they were equivalent in safety as other forms of treatment for hernias;

j. They consistently under-reported, underestimated, withheld, and downplayed serious dangers of the Hernia Mesh Devices and misrepresented its efficacy and safety to the medical and health community, Health Canada, the Plaintiff, the Class Members, and the public in general;

k. They failed to provide adequate warnings regarding the need to periodically test and monitor the patient who was surgically implanted with the Hernia Mesh Devices;

l. They failed to provide adequate updated and current information to Class Members and their physicians respecting the risks of the Hernia Mesh Devices as such information became available;

m. They improperly concealed from, and/or misrepresented information to the medical and health community, Health Canada, the Plaintiff, the Class Members, and the public in general that the risks associated with the Hernia Mesh Devices would exceed the risks of other available hernia mesh devices and/or alternatives to hernia mesh;

n. After receiving actual or constructive notice of the problems associated with the Hernia Mesh Devices, they failed to issue adequate warnings, to publicize the problem and otherwise act in a timely manner to alert the public, the Class Members and their physicians, of the medical devices' inherent dangers;

o. They disregarded reports of Hernia Mesh Injuries among patients;

p. They failed to monitor, investigate, evaluate, review, and follow-up on reports of adverse reactions to the surgical implantation of the Hernia Mesh Devices in Canada and around the world,

q. They falsely stated and/or implied that the Hernia Mesh Devices were safe when they knew or ought to have known that this representation was inaccurate;

r. They failed to establish any adequate procedures to educate their sales representatives as well as physicians respecting the risks associated with the medical devices;

s. They provided incomplete and insufficient training and information to physicians regarding the Hernia Mesh Devices and the aftercare of patients implanted with the Hernia Mesh Devices;

t. They failed to design a safe, effective procedure for the removal of the Hernia Mesh Devices or to determine if a safe, effective procedure for removal of the Hernia Mesh Devices exists;

u. They failed to accurately and promptly disclose to Health Canada information relating to Hernia Mesh Injuries associated with the Hernia Mesh Devices and to modify the Hernia Mesh Devices' representations accordingly in a timely manner;

v. They failed to timely recall the Hernia Mesh Devices, publicize the problems and otherwise act properly and in a timely manner to alert the public of the inherent dangers associated therewith, including, the Dangerous Complications;

w. They deprived patients of a chance for safe, effective and/or successful alternative treatments

x. They continue to negligently research, develop, design, manufacture, test, produce, supply, market, label, package, promote, advertise, import, distribute, and/or sell the Hernia Mesh Devices after the Defendants knew or should have known its significant and Dangerous Complications (particularly so from increasing reports thereof); and

y. In all circumstances of this case, they applied callous and reckless disregard for the health and safety of human beings, including the Plaintiff, and Class Members;

X. Summative Remarks

135. Despite the vast availability of knowledge clearly indicating that surgical implantation of the Hernia Mesh Devices is causally-related to Hernia Mesh Injuries, the Defendants not only failed to warn Class Members, but instead incongruously promoted and marketed the Hernia Mesh Devices as a safe and effective medical device, effectively appropriating the ability of doctors and patients to make informed decisions regarding their health.

136. The Defendants concealed and failed to completely disclose their knowledge that the Hernia Mesh Devices were associated with or could cause Hernia Mesh Injuries as well as their knowledge that they had failed to fully test or study said risk.

137. The Defendants ignored the association between the use of the Hernia Mesh Devices and the risk of Hernia Mesh Injuries.

138. The Defendants researched, developed, designed, manufactured, tested, produced, supplied, marketed, labelled, packaged, promoted, advertised, imported, distributed, and/or sold the Hernia Mesh Devices with the Design Defect coupled with active misrepresentations about its safety in Canada, including within the province of Ontario.

139. The Defendants failed to disclose and/or actively concealed, despite a wealth of longstanding knowledge, that the Hernia Mesh Devices are defective and unsafe in order to increase their profits.

140. The Defendants continue to research, develop, design, manufacture, test, produce, supply, market, label, package, promote, advertise, import, distribute, and/or sell the Hernia Mesh Devices throughout Canada, including within the province of Ontario, with the Design Defect coupled with active misrepresentations about its safety.

141. The Defendants placed the Hernia Mesh Devices into the stream of commerce in Ontario and elsewhere in Canada with the expectation that it would be surgically implanted in persons, such as the Plaintiff and Class Members.

142. The Hernia Mesh Devices were at all times utilized and implanted in a manner foreseeable to the Defendants as they generated the instructions for use, created the procedures for implanting the devices, and trained implanting physicians.

143. Feasible and suitable alternatives to the Hernia Mesh Devices have existed at all relevant times that do not present the same frequency or severity of risks as do the Hernia Mesh Devices;

144. The Class Members have suffered and will suffer injuries, losses or damages as a result of the Defendants' conduct.

145. The Plaintiff and Class Members would not have allowed the Hernia Mesh Devices to be surgically implanted in their bodies were it known they were unsafe.

146. The Defendants concealed material information regarding the truth about the existence and nature of the Design Defect from the medical and health community, Health Canada, the Plaintiff, the Class Members, and the public in general at all times, even though they knew or should have known about the Design Defect and knew or should have known that information about the Design Defect would be important to a reasonable person.

THE REPRESENTATIVE PLAINTIFF'S EXPERIENCE

147. On November 11, 2003, Mr. McWilliams visited a doctor as he was experiencing an inguinal hernia in his lower left groin.

148. On December 1, 2003, Mr. McWilliams underwent an open hernia repair surgery at the Credit Valley Hospital at 2200 Eglinton Avenue West, in Mississauga, Ontario, during which time he was surgically implanted with a PerFix Plug (Ref 0112770, Lot 43DND159). The surgery entailed a two-day hospital stay.

149. Mr. McWilliams believed that all the equipment, medications and other material used during the surgery, which included the Hernia Mesh Device, were the most appropriate choices for surgery and would provide him with a reasonable standard of care.

150. Within the first year of the surgery, Mr. McWilliams began to feel a tightness in his lower left abdomen (where the Hernia Mesh Device had been surgically implanted).

151. Mr. McWilliams went back to the doctor who had performed his hernia repair surgery to try to find out what was wrong with him, but the doctor did not find anything wrong and, therefore, could not help him.

152. By the second year, the pain increased and over the next few years, the pain extended down into his left testicle. During this time, he experienced a gradual inability to empty his bladder, to which led to him needing to self-catheterize 3 times per day in order to do so.

153. In 2007, Mr. McWilliams underwent a pelvic and testicular ultrasound, but it did not reveal that the Hernia Mesh Device was the cause of his injuries; the cause of his injury was unknown and was certainly not thought to be related to his Hernia Mesh Device.

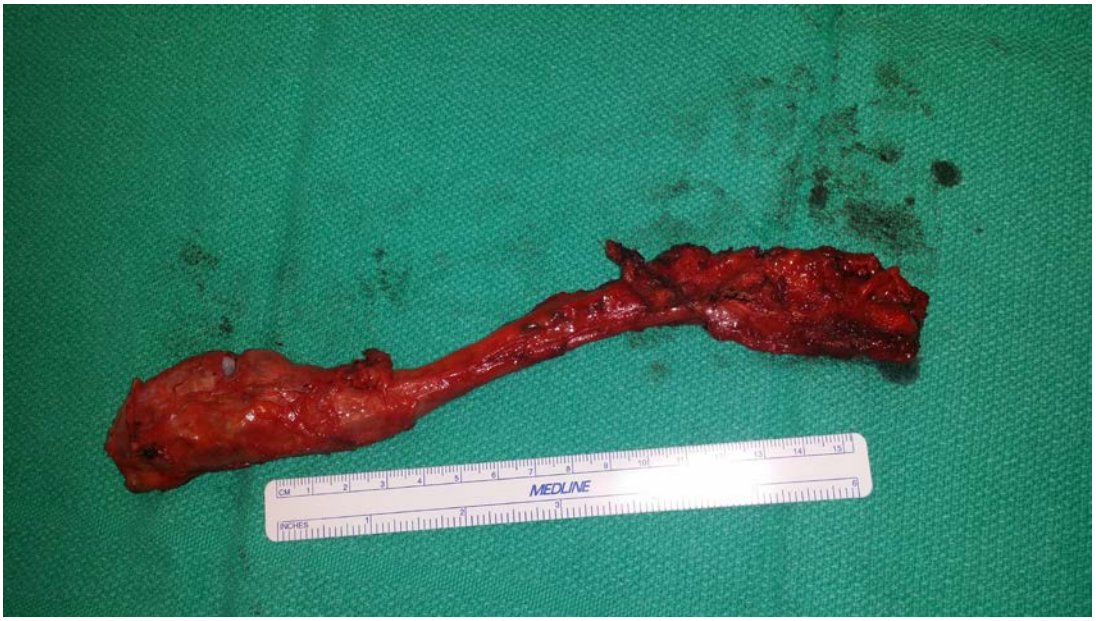
154. The increasing pain interfered with his regular functioning and mobility, which in turn affected his personal life.

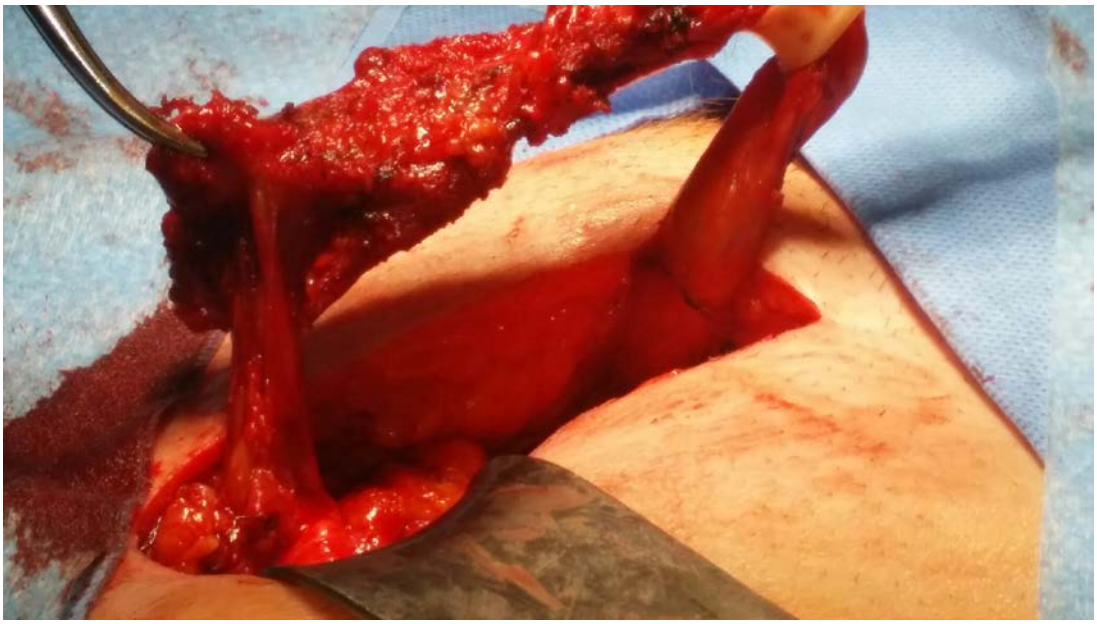
155. On September 23, 2015, Mr. McWilliams visited a urologist in Oakville, Ontario who for the first time made a connection between his injuries and the implantation of the Hernia Mesh Device.

156. On February 1, 2016, Mr. McWilliams had a MRI performed on his pelvic area, which revealed a "significant reaction around the mesh" and "nonspecific fascial thickening overlying the hernia repair". The MRI was performed at the Oakville-Trafalgar Memorial Hospital – Department of Diagnostic Imaging at 3001 Hospital Gate in Oakville, Ontario.

157. After many visits to many doctors and specialists, in October 2016 (13 years later), Mr. McWilliams visited Dr. Morrison who informed him that his injuries were, in fact, caused by the Hernia Mesh Device that had been surgically implanted inside his body many years earlier and that it must be removed.

158. In October 2016, Mr. McWilliams underwent surgery in order to remove the Hernia Mesh Device from his body. Unfortunately, it was then discovered that the Hernia Mesh Device had wrapped around his testicular cord, necessitating the removal of his left testicle. The surgery entailed a two-day hospital stay.





159. Mr. McWilliams has experienced and continues to experience physical and mental stress on himself and on his relationship with his wife, from whom he is currently separated. His ability to have sexual relations has been drastically diminished and his work as a home renovator has been greatly limited due to his physical state.

160. Although the Hernia Mesh Device has been removed, he continues to have chronic discomfort and he is unable to lift heavy objects.

161. The removal of his testicle has affected both his physical and mental state as he is extremely self-conscious about his physical appearance having only one testicle.

162. Mr. McWilliams used to be involved in sports; however, the pain from the Hernia Mesh Device forced him to give this up.

163. Mr. McWilliams has only recently discovered from his own online research that Hernia Mesh Devices have been linked to the Dangerous Complications.

164. At no time was Mr. McWilliams made aware of the risk of Hernia Mesh Injuries associated with the surgical implantation of the Hernia Mesh Devices.

165. Had the Defendants properly disclosed the risks associated with the Hernia Mesh Devices, Mr. McWilliams would not have been exposed to the Dangerous Complications. Further, had Mr. McWilliams been made aware of the risks of the Dangerous Complications, he would not have had to suffer in the dark for 13 years, with no explanation for the cause, gradually getting worse and worse, and could have avoided the Hernia Mesh Device from wrapping around his spermatic cord and would likely not have had to remove his testicle and would not have experienced such grave complications.

166. Mr. McWilliams is aware that, in addition to the present class action, several lawsuits have been filed in the United States for the same product due to the Design Defect associated with the Hernia Mesh Devices and due to the Defendants' conduct related thereto.

167. As a direct and proximate result of the Hernia Mesh Device Design Defect and the Defendants' wrongful conduct as alleged herein, the Plaintiff sustained and continues to suffer damages, including, but not limited to difficulty or inability to urinate, severe and chronic groin and testicular pain, pain with sex (dyspareunia), testicular amputation, blood loss, nausea, chronic physical pain, surgical correction, mental anguish, physical impairment, physical disfigurement, diminished quality and enjoyment of life and increased risk of health problems, as well as the need for continued medical treatment, monitoring and/or medications, loss of income and loss of future

income, the apportioned cost of the medical procedures caused by the Hernia Mesh Device, pain, suffering, anxiety, fear, trouble, annoyance, and inconvenience.

CAUSES OF ACTION

A. Strict Liability

168. The Defendants are strictly liable to the Plaintiff and Class Members for the reasons that follow:

(a) The Defendants researched, developed, designed, manufactured, tested, produced, supplied, marketed, labelled, packaged, promoted, advertised, imported, distributed, and/or sold the Hernia Mesh Devices as hereinabove described;

(b) The Hernia Mesh Devices were expected to and did reach the Class Members without substantial change in the condition in which they were was researched, developed, designed, manufactured, tested, produced, supplied, marketed, labelled, packaged, promoted, advertised, imported, distributed, and/or sold by the Defendants;

(c) At all times, the Hernia Mesh Devices were in an unsafe, defective, and inherently dangerous condition, which implantation thereof was dangerous to human beings, including, the Plaintiff herein and Class Members;

(d) The Hernia Mesh Devices were manufactured defectively in that it left the hands of Defendants in a defective condition and was unreasonably dangerous to its intended users;

(e) The Hernia Mesh Devices were suffering from a serious manufacturing and/or design defect in that, when they left the hands of the Defendants, they were unreasonably and unnecessarily dangerous, and at minimum, were more dangerous than an ordinary person would expect;

(f) At all times relevant hereto, the Hernia Mesh Devices were in a defective condition and were unsafe and the Defendants knew or had reason to know that said product was defective and unsafe, especially when used in the form and manner as provided by the Defendants;

(g) At the time of the surgical implantation of the Hernia Mesh Device in the Plaintiff's groin, it was being used for the precise purposes and in such a manner as normally intended;

(h) The Defendants, equipped with this knowledge, voluntarily designed the Hernia Mesh Devices in a dangerous condition for implantation into human beings;

(i) The Defendants created a product unreasonably dangerous for its normal, intended use;

(j) The Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use and at least such a duty extended to not creating a product that was unreasonably dangerous for its normal, intended use;

(k) Class Members were entitled to expect that the Hernia Mesh Devices were safe for surgical implantation, convenient, and effective;

(l) The Defendants researched, developed, designed, manufactured, tested, produced, supplied, marketed, labelled, packaged, promoted, advertised, imported, distributed, and/or sold a defective product which created an unreasonable risk to the health of Class Members, and the Defendants are therefore strictly liable for the injuries sustained, including the Dangerous Complications;

(m) The risks inherent in the design of the Hernia Mesh Devices, for example, the use of polypropylene and/or the bioresorbable coating thereon, outweigh any possible benefits of its design and such defects were material contributing causes of the injuries and losses of Class Members;

(n) At the time of the injury and loss to Class Members, the Hernia Mesh Devices were being used for the purpose and manner for which they were intended – i.e. surgical implantation inside the human body for hernia repair – and Class Members could not, through the exercise of reasonable care and diligence, have discovered the Hernia Mesh Device defects herein mentioned and/or perceived its danger;

(o) The lack of adequate warnings and/or testing on the part of the Defendants materially contributed to the defective nature of the device;

(p) The Hernia Mesh Devices were defective due to inadequate post-marketing surveillance and/or warnings because, after the Defendants knew or should have known of the Dangerous Complications related to the surgical implantation of the Hernia Mesh Devices, they failed to provide adequate warnings to the medical and health community, to Health Canada, to the Plaintiff, to the Class Members, and to the public in general, and continued to improperly design, manufacture, produce, supply, market, label, package, promote, advertise, import, distribute, and/or sell their products;

169. By reason of the foregoing, the Defendants are strictly liable in tort to the Class Members for the research, development, design, manufacture, testing, production, supply, marketing, labelling, packaging, promotion, advertising, importation, distribution, and/or sale of a defective product, being the Hernia Mesh Devices.

170. The Defendants' defective design and manufacture, coupled with inadequate warnings regarding the Hernia Mesh Devices were acts that amount to wilful, wanton, and/or reckless conduct.

171. The Design Defect was, at minimum, a substantial factor in causing Class Members' and Plaintiff's injuries.

172. As a result of the foregoing acts and omissions, Class Members were exposed to and/or suffered Dangerous Complications as well as fear of developing any of the medical consequences.

B. Tort of Civil Negligence

173. The Defendants, at all times, owed a positive legal duty to use reasonable care to perform their legal duty to the Plaintiff and to Class Members, including a duty to assure that the Hernia Mesh Devices would not cause Class Members to suffer a risk of unreasonable and Dangerous Complications.

174. The Defendants also failed to exercise reasonable care in their research, development, design, manufacture, testing, production, supply, marketing, labelling, packaging, promotion, advertising, importation, distribution, and/or sale of the Hernia Mesh Devices in that the Defendants knew or should have known that surgical implantation of the Hernia Mesh Devices into the human body created a high risk of unreasonable and Dangerous Complications.

175. In addition, the Defendants were aware that the medical and health community, Health Canada, the Plaintiff, Class Members, and the public relied on them to provide truthful and accurate information regarding the safety and efficacy of the Hernia Mesh Devices.

176. By its acts described herein, the Defendants failed to take reasonable care to ensure that the Hernia Mesh Devices were safe and effective.

177. The Defendants breached their duty of care to the Plaintiff and to the Class Members by offering for sale a device that was not fit for the particular purpose for which it was intended.

178. The Defendants failed to meet the standard of care required in all the circumstances and were negligent in the research, development, design, manufacture, testing, production, supply, marketing, labelling, packaging, promotion, advertising, importation, distribution, and/or sale of the Hernia Mesh Devices in that:

(a) They knew or should have known that the surgical implantation of the Hernia Mesh Devices created the risk of the Hernia Mesh Injuries;

(b) They failed to ensure that the Hernia Mesh Devices were fit for their intended and/or reasonably foreseeable use and that they were not dangerous to users;

(c) They failed to conduct proper, adequate, appropriate, and thorough testing to determine whether and to what extent the implantation of the Hernia Mesh Devices poses serious risks, including the Hernia Mesh Injuries;

(d) They failed to adequately test the Hernia Mesh Devices to ensure that they were acceptably safe and free from defects prior to releasing them into the Canadian marketplace;

(e) They failed to properly, adequately, appropriately, and correctly warn the medical and health community, Health Canada, the Plaintiff, Class Members, and the public in general of the significant and dangerous risks associated with the Hernia Mesh Devices and the severity thereof, both prior to releasing it into the Canadian marketplace and afterward;

(f) They failed to use proper care in researching, developing, designing, manufacturing, testing, producing, and supplying their products so as to avoid posing unnecessary health risks;

(g) They failed to conduct adequate pre-clinical and clinical testing, post-marketing surveillance and follow-up studies to determine the safety of the medical devices;

(h) They failed to advise the medical and scientific communities that the surgical implantation of the Hernia Mesh Devices could result in severe side effects, including but not limited to, the Hernia Mesh Injuries;

(i) They misrepresented that the Hernia Mesh Devices were safe and that they were equivalent in safety as other forms of treatment for hernias;

(j) They consistently under-reported, underestimated, withheld, and downplayed the serious dangers of the Hernia Mesh Devices and misrepresented its efficacy and safety to the medical and health community, Health Canada, the Plaintiff, the Class Members, and the public in general;

(k) They failed to provide adequate warnings regarding the need to periodically test and monitor the patient who was surgically implanted with the Hernia Mesh Devices;

(l) They failed to provide adequate updated and current information to Class Members and their physicians respecting the risks of the Hernia Mesh Devices as such information became available;

(m) They improperly concealed from, and/or misrepresented information to the medical and health community, Health Canada, the Plaintiff, the Class Members, and the public in general that the risks associated with the Hernia Mesh Devices would exceed the risks of other available hernia mesh devices and/or alternatives to hernia mesh;

(n) After receiving actual or constructive notice of the problems associated with the Hernia Mesh Devices, they failed to issue adequate warnings, to publicize the problem and otherwise act in a timely manner to alert the public, the Class Members and their physicians, of the medical devices' inherent dangers;

(o) They disregarded reports of Hernia Mesh Injuries among patients;

(p) They failed to monitor, investigate, evaluate, and follow-up on adverse reactions to the surgical implantation of the Hernia Mesh Devices,

(q) They falsely stated and/or implied that the Hernia Mesh Devices were safe when they knew or ought to have known that this representation was inaccurate;

(r) They failed to accurately and promptly disclose to Health Canada information relating to Hernia Mesh Injuries associated with the Hernia Mesh Devices and to modify the Hernia Mesh Devices' representations accordingly in a timely manner;

(s) They failed to timely recall the Hernia Mesh Devices, publicize the problems and otherwise act properly and in a timely manner to alert the public of the inherent dangers associated therewith, including the Dangerous Complications;

(t) They deprived patients of a chance for safe, effective and/or successful alternative treatments;

(u) They continue to negligently research, develop, design, manufacture, test, produce, supply, market, label, package, promote, advertise, import, distribute, and/or sell the Hernia Mesh Devices after Defendants knew or should have known its significant and Dangerous Complications (particularly so from increasing reports thereof);

(v) They failed to conform their conduct in line with applicable disclosure and reporting requirements pursuant to the *Food and Drugs Act* and its associated regulations;

(w) They placed their commercial interests over the Plaintiff and Class Members' safety; and

(x) In all of the circumstances of this case, they applied callous and reckless disregard for the health and safety of human beings, including the Plaintiff and Class Members.

179. The Defendants knew or should have known that the Hernia Mesh Devices exposed the Plaintiff and Class Members to the Dangerous Complications.

180. The circumstances of the Defendants being in the business of researching, developing, designing, manufacturing, testing, producing, supplying, marketing, labelling, packaging, promoting, advertising, importing, distributing, and/or selling the Hernia Mesh Devices and placing the Hernia Mesh Devices into the Canadian stream of commerce are such that the

Defendants were in a position of legal proximity to the Class Members and were therefore under an obligation to be fully aware of and disclose adequate information about their safety and efficacy.

181. It was certainly reasonably foreseeable that if the Defendants were negligent in their duty to provide accurate information regarding the safety of the Hernia Mesh Devices, that the Plaintiff and Class Members could and would sustain injury and damages and this, in fact, did materialize.

182. It was reasonably foreseeable that failure by the Defendants to meet its duty of care researching, developing, designing, manufacturing, testing, producing, supplying, marketing, labelling, packaging, promoting, advertising, importing, distributing, and/or selling the Hernia Mesh Devices, and to thereafter to monitor their performance following market introduction (and to take corrective measures when required) would cause harm to the Plaintiff and the members of the Class.

183. By virtue of the acts, omissions and misrepresentations described above, the Defendants were negligent and caused damage to the Plaintiff and to the Class Members.

C. Breach of Express Warranty

184. The Defendants expressly warranted to the medical and health community, Health Canada, the Plaintiff, the Class Members, and the public in general that the Hernia Mesh Devices were safe, effective, and fit for use for their intended purposes; i.e. surgical implantation inside patients' bodies during a hernia repair surgery, such as the Plaintiff and Class Members.

185. The Defendants expressly represented that the Hernia Mesh Devices was of merchantable quality, that they did not pose any Dangerous Complications in excess of those risks associated with other forms of hernia repair and that they were adequately tested and fit for their intended use.

186. The Hernia Mesh Devices suffer from the Design Defect which poses Dangerous Complications, all of which were not disclosed by the Defendants and further, were actively concealed.

187. The Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that the Hernia Mesh Devices were not safe and fit for the intended use and, in fact, caused serious injuries including the Dangerous Complications.

188. The medical and health community, Health Canada, the Plaintiff, the Class Members, and the public in general relied upon the representations and express warranties of the Defendants with regards to the Hernia Mesh Devices.

189. As a result of the foregoing acts and omissions, the Plaintiff and Class Members suffered the Dangerous Complications.

D. Breach of Implied Warranties

190. At all times herein mentioned, the Defendants researched, developed, designed, manufactured, tested, produced, supplied, marketed, labelled, packaged, promoted, advertised, imported, distributed, and/or sold the Hernia Mesh Devices for surgical implantation.

191. At the time that the Defendants researched, developed, designed, manufactured, tested, produced, supplied, marketed, labelled, packaged, promoted, advertised, imported, distributed, and/or sold the Hernia Mesh Devices for implantation into Class Members' bodies, they knew of the use for which the Hernia Mesh Devices was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

192. The Defendants represented and warranted to the medical and health community, Health Canada, the Plaintiff, the Class Members, and the public in general that the Hernia Mesh Devices were safe and of merchantable quality and fit for the ordinary purpose for which said product was to be used.

193. Said representations and warranties aforementioned were false, misleading, and inaccurate in that the Hernia Mesh Devices were unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.

194. The medical and health community, Health Canada, the Plaintiff, the Class Members, and the public in general did rely on said implied warranty of merchantability of fitness for a particular use and purpose.

195. Class Members and their physicians and healthcare professionals reasonably relied upon the skill and judgment of Defendants as to whether the Hernia Mesh Devices were of merchantable quality and safe and fit for their intended use.

196. The Hernia Mesh Devices were placed into the stream of commerce by the Defendants in a defective, unsafe, and inherently dangerous condition.

197. The Defendants breached the aforesaid implied warranties and the Hernia Mesh Devices were not fit for its intended purposes and uses.

198. As a result of the foregoing acts and omissions, Class Members suffered serious and Dangerous Complications.

E. Failure to Warn

199. Defendants researched, developed, designed, manufactured, tested, produced, supplied, marketed, labelled, packaged, promoted, advertised, imported, distributed, and/or sold the Hernia Mesh Devices and therefore had a duty to warn of the risks associated with the surgical implantation of the Hernia Mesh Devices.

200. The Defendants failed to warn the medical and health community, Health Canada, the Plaintiff, the Class Members, and the public in general of the risks associated with the Hernia Mesh Devices. These risks include that the implantation of the Hernia Mesh Devices would cause a serious risk of the Dangerous Complications.

201. The Defendants failed to provide timely and reasonable warnings regarding the safety and efficacy of the Hernia Mesh Devices. Had they done so, proper warnings would have been heeded and no health care professional, including the Plaintiff's and Class Members' physicians, would have used the Hernia Mesh Devices for surgical implantation, and no patient, including the Plaintiff and Class Members, would have consented to it.

202. The failure to provide timely and reasonable warnings, instructions, and information regarding the Hernia Mesh Devices to the Plaintiff and to Class Members and/or to their physicians rendered the Hernia Mesh Devices even more unreasonably dangerous.

203. The Plaintiff states that his damages and the damages of other Class Members were caused by the Defendants' failure to warn, which includes, but is not limited to, the following:

a) They failed to provide the medical and health community, Health Canada, the Plaintiff, the Class Members, and the public in general with proper, adequate, and/or fair warning of the risks associated with the surgical implantation of the Hernia Mesh Devices, including the Dangerous Complications;

b) They failed to provide any or any adequate updated and/or current information to the medical and health community, Health Canada, the Plaintiff, the Class Members, and the public in general respecting the Dangerous Complications associated with the Hernia Mesh Devices as such information became available from time to time;

c) They failed to provide adequate warnings of the potential risks associated with the Hernia Mesh Devices;

d) They failed to issue adequate warnings, issue a timely recall of the devices, publicize the problem and to otherwise act properly and in a timely manner to alert the public, including adequately warning persons already implanted with the Hernia Mesh Devices and/or about to be surgically implanted with the devices and their physicians or other health care providers of their inherent dangers;

e) They failed to perform or to otherwise facilitate adequate testing, failed to reveal or concealed testing and research data, and/or selectively and misleadingly revealed and/or analyzed testing and research data on the Hernia Mesh Devices;

f) They failed to provide complete and accurate clinical and non-clinical data to Health Canada throughout the approval process for the Hernia Mesh Devices and subsequent to its approval, including when they submitted to Health Canada for premarket approval of the Hernia Mesh Devices and subsequent to the issuance by Health Canada of the approval thereof;

g) They failed to promptly report to Health Canada all of the adverse events that came to be reported to the Defendants with regards to the Hernia Mesh Devices subsequent to their approval in Canada;

h) They failed to establish any adequate procedures to educate their sales representatives and prescribing physicians or other health care providers respecting the risks associated with the surgical implantation of the Hernia Mesh Devices; and

i) They failed to conform with applicable disclosure and reporting requirements pursuant to the *Food and Drugs Act*, RSC 1985, c F-27 and its associated regulations.

204. The design of the Hernia Mesh Devices with polypropylene and at times, with the bioresorbable coating, makes the Hernia Mesh Devices unreasonably dangerous when used in the way it is ordinarily used and it is dangerous to an extent beyond that which would be contemplated by the ordinary, reasonable person, with the ordinary knowledge common to the community as to its characteristics.

205. At all times relevant to this action, economically and technologically feasible safer alternatives existed, which in reasonable medical probability:

a) Would have prevented or significantly reduced the risk of the Plaintiff's and Class Member's risk of Dangerous Complications (including additional surgical procedures to remove the implant); and

b) Would have treated the existing hernia.

206. Had the Defendants adequately warned the medical and health community, Health Canada, the Plaintiff, the Class Members, and the public in general, proper warning would have been heeded and no health care professional, including the Plaintiff's physicians, would have surgically implanted the Hernia Mesh Devices and no patient, including the Plaintiff, would have allowed for it to be implanted into their bodies.

207. The failure to provide timely and reasonable warnings, instructions, and information regarding the Hernia Mesh Devices to the medical and health community, Health Canada, the Plaintiff, the Class Members, and the public in general, rendered the Hernia Mesh Devices unreasonably dangerous. As a direct result of Defendants' conduct, the Plaintiff has suffered and continues to suffer serious and permanent injuries.

F. Tort of Fraudulent Misrepresentation

208. The Defendants falsely and fraudulently represented to the medical and healthcare community, and to the Plaintiff, to Class Members, to Health Canada, and the public in general,

that the Hernia Mesh Devices had been tested and had been found to be safe and/or effective for surgical implantation during a hernia repair surgery. The Defendants further misrepresented that that patients, Class Members, the Plaintiff, and/or the medical and healthcare community could safely implant the Hernia Mesh Devices without the Dangerous Complications.

209. The representations made by the Defendants were, in fact, false.

210. When said representations were made by the Defendants, they knew those representations to be false or, at a minimum, they wilfully, wantonly and recklessly disregarded whether the representations were true.

211. These representations were made by the Defendants with the intent of deceiving the medical and health community, Health Canada, the Plaintiff, the Class Members, and the public in general and were made with the intent of inducing them to recommend, purchase, and/or implant the Hernia Mesh Devices during hernia repair surgery, all of which evinced a callous, reckless, wilful, depraved indifference to the health, safety and welfare of Class Members.

212. Based on said representations, the Hernia Mesh Devices was surgically implanted into the Plaintiff and Class Members, thereby causing them to be exposed to the Dangerous Complications.

213. The Defendants knew and were aware or should have been aware that the Hernia Mesh Devices had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

214. The Defendants knew or should have known that the Hernia Mesh Devices had a potential to, could, and would cause severe and grievous injury to human beings implanted with said

products, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings and misleading instructions.

215. The Defendants brought the Hernia Mesh Devices to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Plaintiff and Class Members.

G. Tort of Negligent Misrepresentation

216. The tort of negligent misrepresentation can be made out as:

(a) There was a relationship of proximity in which failure to take reasonable care might foreseeably cause loss or harm to the Plaintiff and to the Class;

(b) The Defendants made representations and/or omissions that were untrue, inaccurate and/or misleading;

(c) The Defendants acted negligently in making the representations and/or omissions;

(d) The representations and/or omissions were relied upon reasonably; and

(e) The Plaintiff and the Class sustained damages as a result of their reliance.

217. The Defendants represented to the medical and health community, Health Canada, the Plaintiff, the Class Members, and the public in general that the Hernia Mesh Devices had been tested and had been found to be safe and effective for surgical implantation during hernia repair surgery – these representations were untrue as set forth herein.

218. The Defendants failed to exercise ordinary care in the representation of the Hernia Mesh Devices and instead, negligently misrepresented the Hernia Mesh Devices' unreasonable, Dangerous Complications.

219. At the time that the Defendants made the misrepresentations herein alleged, they had no reasonable grounds for believing them to be true as there was ample evidence to the contrary set forth in detail above.

220. The Defendants made the Representation herein alleged with the intention of inducing the Hernia Mesh Devices to be surgically implanted into the Plaintiff and into the Class Members.

221. The representations and/or omissions were relied upon and, in reliance thereupon, the Hernia Mesh Devices was surgically implanted into the Plaintiff and Class Members. Said reliance was reasonable.

222. By reason of the foregoing, Plaintiff and each member of the Class are entitled to recover damages and other relief from the Defendants.

STATUTORY REMEDIES

223. The Defendants are in breach of the federal *Competition Act* and the *Food and Drugs Act*.

224. The Plaintiff pleads and relies upon trade legislation and common law, as it exists in this jurisdiction and the equivalent/similar legislation and common law in other Canadian provinces and territories. The Class Members have suffered injury, economic loss and damages caused by or materially-contributed to by the Defendants' inappropriate and unfair business practices.

A. Breach of the *Competition Act*

225. At all times relevant to this action, the Defendants' businesses were "business(es)" and the Hernia Mesh Devices were "product(s)" within the meaning of that term as defined in s. 2 of the *Competition Act*.

226. The Defendants' acts are in breach of s. 52 of Part VI of the *Competition Act*, were and are unlawful, and render the Defendants liable to pay damages and costs of investigation pursuant to s. 36 of the *Competition Act*.

227. The Defendants made the Representation to the public and in so doing breached s. 52 of the *Competition Act* because the Representation:

(a) Was made for the purpose of promoting, directly or indirectly, the use of a product or for the purpose of promoting, directly or indirectly, the business interests of the Defendants;

(b) Was made to the public;

(c) Was false and misleading in a material respect; and

(d) Stated approval, performance characteristics, uses, benefits and/or qualities of the Hernia Mesh Devices that were false and not based on adequate and proper testing and stated a particular standard and/or quality that was not based on adequate and proper testing.

228. The Representation was relied upon and the Plaintiff and Class Members suffered damages and loss.

229. Pursuant to s. 36 of the *Competition Act*, the Defendants are liable to pay the damages which resulted from the breach of s. 52.

230. Pursuant to s. 36 of the *Competition Act*, the Plaintiff and Class Members are entitled to recover their full costs of investigation and substantial indemnity costs paid in accordance with the *Competition Act*.

231. The Plaintiff and Class Members are also entitled to recover as damages or costs, in accordance with the *Competition Act*, the costs of administering the plan to distribute the recovery in this action and the costs to determine the damages of each Class Member.

B. Breach of the *Food and Drugs Act*

232. At all times relevant to this action, the Hernia Mesh Devices was a "device" within the meaning of that term as defined in s. 2 of the *Food and Drugs Act*.

233. At all times relevant to this action, the Defendants' representations were "advertisement(s)" within the meaning of that term as defined in s. 2 of the *Food and Drugs Act*.

234. Section 19 of the *Food and Drugs Act* prohibits the sale of any device, such as the Hernia Mesh Devices, that when used according to directions or under such conditions as are customary or usual, may cause injury to the health of the purchaser or user thereof.

235. Section 20 of the *Food and Drugs Act* prohibits the labelling, packaging, sale or advertisement of any device, such as the Hernia Mesh Devices, in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its design, construction, performance, intended use, quantity, character, value, composition, merit or safety.

236. At material times, the Defendants violated section 19 of the *Food and Drugs Act* by selling the Hernia Mesh Devices that, when used under regular conditions creates the risk of the Dangerous Conditions.

237. At material times, the Defendants violated section 20 of the *Food and Drugs Act* by labelling, packaging, selling, and advertising the Hernia Mesh Devices in a false, misleading and/or deceptive manner or in a manner that is likely to create an erroneous impression regarding its design, construction, performance, intended use, character, composition, merit and/or safety.

238. As a result of violating the *Food and Drugs Act*, the Defendants caused the Hernia Mesh Devices to be surgically implanted inside the Plaintiff and Class Members, thereby causing severe injuries and damages, as previously described herein.

CAUSATION

239. The Defendants knew or should have known that Class Members would foreseeably suffer injury as a result of their failure to exercise ordinary care and there is therefore a sufficient relationship of proximity.

240. The Plaintiff and Class Members, being patients undergoing hernia repair surgery in Canada, were reasonably in a position to be harmed by the surgical implantation of the Hernia Mesh Devices.

241. The acts, omissions, wrongdoings, and breaches of legal duties and obligations of the Defendants directly and proximately caused the Plaintiff's and Class Members' injuries and damages.

242. The Plaintiff pleads that by virtue of the acts, omissions and breaches of legal obligations as described above, they are entitled to legal and/or equitable relief against the Defendants, including damages, consequential damages, specific performance, attorneys' fees, costs of suit and other relief as appropriate in the circumstances.

DAMAGES

243. By reason of the acts, omissions and breaches of legal obligations of the Defendants, the Plaintiff and Class Members have suffered economic loss and damages, the particulars of which include, but are not limited to, the following general, compensatory and punitive damages:

A. Special Damages (Pecuniary Damages)

(a) Out-of-pocket expenses incurred or to be incurred, including those connected with hospital stays, medical treatment, life care, medications, medical monitoring services, and the diagnosis and treatment of the Dangerous Complications;

(b) Loss of income and loss of future income; and

(c) Such further and other damages the particulars of which will be particularized prior to trial.

B. General Damages (Non-Pecuniary Damages)

244. By reason of the acts, omissions and breaches of legal obligations of the Defendants, the Plaintiff and Class Members have suffered injury, non-economic loss and damages, the particulars of which include:

(a) At least one of the Hernia Mesh Injuries;

(b) Severe physical pain and mental anguish;

(c) Pain, suffering, anxiety, fear, loss of quality and enjoyment of life, embarrassment, increased risk of health, mental, and/or emotional problems, and damage to and/or loss of reputation; and

(d) Physical impairment and/or disfigurement.

245. As a result of the Defendants' negligence, putative class members are entitled to damages pursuant to, *inter alia*, the *Tort-feasors Act*, RSA 2000 c T-5, the *Fatal Accidents Act*, RSA 2000, c F-8, *The Fatal Accidents Act*, CSSM c F50, the *Fatal Accidents Act*, RSNB 1973, c F-7, as repealed by *Fatal Accidents Act*, SNB 2012, c 104, the *Fatal Accidents Act*, RSNL 1990, c F-6, the *Fatal Injuries Act*, RSNS 1989, c 163, the *Fatal Accidents Act*, RSPEI 1988, c F-5, as amended by SPEI 2008, c 8, s II, *The Fatal Accidents Act*, RSS 1978, c F-11, the *Fatal Accidents Act*, RSNWT 1988, c F-3, the *Fatal Accidents Act*, RSNWT (Nu) 1988, c F-3, the *Fatal Accidents Act*, RSY

2002, c 86, the *Family Compensation Act,* RSBC 1996, c 126, and the regulations thereunder and amendments thereto.

246. Some of the expenses related to the medical treatment that Class Members have undergone, and will continue to undergo, have been borne by the various provincial health insurers, including the Ontario Ministry of Health and Long-Term Care ("MOHLTC").

247. As a result of the Defendants' negligence, the various provincial health insurers have suffered and will continue to suffer damages for which they are entitled to be compensated by virtue of their right of subrogation in respect of all past and future insured services. A claim is hereby advanced for the cost of such services under the applicable Provincial and Territorial Legislation including the *Health Care Costs Recovery Act,* SBC 2008, c 27, the *Health Services Insurance Act,* CCSM c H35, the *Health Services Act,* RSNB 1973, c H-3, the *Health Services and Insurance Act,* RSNS 1989, c 197, the *Health Insurance Act,* RSO 1990, c H-6, , and *The Department of Health Act,* RSS 1978, c D-17, the *Health Care Insurance Plan Act,* RSY 2002, c I 07, the *Hospital Insurance and Health and Social Services Administration Act,* RSNWT 1988, c.T-3, the *Hospital insurance and Health and Social Services Administration Act,* RSNWT (Nu) 1988, c.T-3, the *Crown's Right of Recovery Act,* SA 2009, c C-35, the *Hospital and Diagnostic Services Insurance Act,* RSPEI 1988, c H-8, the *Hospital Insurance Agreement Act,* RSNL 1990, c H-7, and the regulations thereunder and amendments thereto.

C. Punitive (Exemplary) and Aggravated Damages

248. The Defendants has taken a cavalier and arbitrary attitude to their legal and moral duties to the Class Members in researching, developing, designing, manufacturing, testing, producing,

supplying, marketing, labelling, packaging, promoting, advertising, importing, distributing, and/or selling the Hernia Mesh Devices with an innate design and/or manufacturing defect to be surgically implanted into other human beings' bodies.

249. At all material times, the conduct of the Defendants as set forth was deliberate and oppressive and the Defendants conducted themselves in a wilful, wanton and reckless manner, without regard for public safety as to warrant a claim for punitive damages. Defendants' acts or omissions described above, when viewed from the standpoint of the Defendants at the time of the act or omission, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to the Plaintiff, Class Members and the community at large.

250. By engaging in such deplorable conduct and tactics, the Defendants committed separate actionable wrongs for which this Honourable Court should voice its disapproval and displeasure with an award of punitive damages.

251. Defendants' acts or omissions, as described herein, were performed with a realization of the imminence of danger and were performed with reckless disregard or complete indifference to the probable result.

252. Defendants had actual, subjective awareness of the risks involved in the above described acts or omissions, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of Plaintiff, Class Members and the community at large.

253. In addition, it should be noted since the Defendants are part of highly revered, multi-billion dollar corporations, it is imperative to avoid any perception that they can evade the law without

impunity. Should the Defendants only be required to disgorge monies which should not have been retained and/or withheld, such a finding would be tantamount to an encouragement to other businesses to commit wrongdoings as well. Punitive and aggravated damages are necessary in the case at hand to be material in order to have a general deterrent effect on other corporations as well as a specific deterrent to the Defendants themselves.

WAIVER OF TORT, UNJUST ENRICHMENT AND CONSTRUCTIVE TRUST

254. The Plaintiff pleads and relies on the doctrine of waiver of tort and states that the Defendants' conduct, including the alleged torts, as well as, breaches of the *Competition Act* and/or the *Food and Drugs Act* constitutes wrongful conduct which can be waived in favour of an election to receive restitutionary or other equitable remedies in the amount of the Defendants' gain therefrom.

255. The Plaintiff reserves the right to elect at the Trial of the Common Issues to waive the legal wrongs and to have damages assessed in an amount equal to the gross revenues earned by the Defendants, the net income received by the Defendants, or a percentage of the sales of the Hernia Mesh Devices.

256. The Defendants have been unjustly enriched as a result of the revenues generated from the sale of the Hernia Mesh Devices and as such, *inter alia*, that:

(a) The Defendants have obtained an enrichment through revenues and profits from the sale of the Hernia Mesh Devices;

(b) The Plaintiff and Class Members have suffered harm; and

(c) The benefit obtained by the Defendants and the harm experienced by the Plaintiff and Class Members has occurred without juristic reason. Since the monies that were received by the Defendants resulted from the Defendants' wrongful acts, there is and can be no juridical reason justifying the Defendants retaining any portion of such monies.

257. Further, or in the alternative, the Defendants are constituted as constructive trustees in favour of the Class Members for all of the monies received because, among other reasons:

(a) The Defendants were unjustly enriched by receipt of the monies paid for the Hernia Mesh Devices;

(b) The Class Members suffered harm by having the Hernia Mesh Devices surgically implanted into their bodies and by having been exposed to the Dangerous Complications;

(c) The monies were acquired in such circumstances that the Defendants may not in good conscience retain them;

(d) Equity, justice and good conscience require the imposition of a constructive trust;

(e) The integrity of the market would be undermined if the court did not impose a constructive trust; and

(f) There are no factors that would render the imposition of a constructive trust unjust.

258. Further, or in the alternative, the Plaintiff claims an accounting and disgorgement of the benefits which accrued to the Defendants.

COMMON ISSUES

259. Common questions of law and fact exist for the Class Members and predominate over any questions affecting individual members of the Class. The common questions of law and fact include:

(a) Do the Hernia Mesh Devices cause, exacerbate or contribute to the Hernia Mesh Injuries? If so, what is the magnitude of this increased risk?

(b) Did any of the Defendants breach a duty to warn Health Canada, Class Members, and/or their physicians about the risks associated with the implantation of the Hernia Mesh Devices? If so, when?

(c) Were the Hernia Mesh Devices researched, developed, designed, manufactured, tested, produced, supplied, marketed, labelled, packaged, promoted, advertised, distributed, and/or sold with defects that increase a patient's risk of the Hernia Mesh Injuries?

(d) Are the Defendants strictly liable for the damages suffered by Class Members?

(e) Do the Defendants owe the Class Members a duty to use reasonable care?

(f) Did the Defendants act negligently in failing to use reasonable care to perform their legal obligations, to, *inter alia*, properly research, develop, design, manufacture, test, produce, supply, market, label, package, promote, advertise, import, distribute, and/or sell safe medical devices, including the Hernia Mesh Devices?

(g) Were the Defendants negligent in the research, development, design, manufacture, testing, production, supply, marketing, labelling, packaging, promotion, advertising, importation, distribution, and/or sale of the Hernia Mesh Devices?

(h) Were the Defendants negligent and/or did they fail in their duty of safety and/or duty to inform imposed upon them as researchers, developers, designers, manufacturers, testers, producers, suppliers, marketers, labellers, packagers, promoters, advertisers, importers, distributers, and/or sellers of the Hernia Mesh Devices?

(i) Did the Defendants fail to conduct, supervise and/or monitor clinical trials for the Hernia Mesh Devices?

(j) Did the Defendants fail to take reasonable care to ensure that the Hernia Mesh Devices would be safe and effective?

(k) Did the Defendants breach their duty of care to the Plaintiff and to the Class Members by offering for sale a device that was not fit for the particular purpose for which it was purchased?

(l) Did the Defendants breach their express and/or implied warranties that the Hernia Mesh Devices were safe when, in fact, they were not?

(m) Are the Hernia Mesh Devices unfit for the purpose for which they were intended?

(n) Did the Defendants intend or foresee that the Plaintiff and/or other Class Members would have the Hernia Mesh Devices surgically implanted into their bodies based on their unfair practices and/or tortious conduct?

(o) Did the Defendants know or should have known about the risks associated with the use of the Hernia Mesh Devices?

(p) Did the Defendants' negligence proximately cause loss or injury and damages?

(q) Did the Defendants knowingly, recklessly or negligently misrepresent to Health Canada, Class Members, and/or their physicians the risks of harm from the implantation of the Hernia Mesh Devices?

(r) Did the Defendants fail to warn the medical and health community, Health Canada, the Plaintiff, the Class Members, and the public in general, of the Dangerous Complications associated with the Hernia Mesh Devices?

(s) Did the Defendants misrepresent the Hernia Mesh Devices as safe or fail to adequately disclose in a timely manner, if at all, their dangerous nature?

(t) Did the Defendants engage in unfair, false, misleading, or deceptive acts or practices regarding the research, development, design, manufacture, testing, production, supply, marketing, labelling, packaging, promotion, advertising, importation, distribution, and/or sale of the Hernia Mesh Devices?

(u) Did the Defendants' acts or practices breach the *Competition Act* and/or the *Food and Drugs Act*?

(v) Have Class Members been damaged by the Defendants' conduct and, if so, what is the proper measure of such damages?

(w) Were the Defendants unjustly enriched?

(x) Should an injunctive remedy be ordered (i) prohibiting the Defendants from continuing to perpetrate their unfair, false, misleading, and/or deceptive conduct, (ii) requiring the Defendants to recall the Hernia Mesh Devices, and (iii) requiring the Defendants to properly disclose the Hernia Mesh Injuries?

(y) Are the Defendants responsible to pay punitive and/or aggravated damages to Class Members and in what amount?

EFFICACY OF CLASS PROCEEDINGS

260. The Class Members are so numerous that joinder into one action is impractical and unmanageable. The Class Members are geographically dispersed and number in the thousands.

Continuing with the Class Members' claim by way of a class proceeding is both practical and manageable and will therefore provide substantial benefits to both the parties and to the Court.

261. Members of the proposed Class have no material interest in commencing separate actions. In addition, given the costs and risks inherent in an action before the courts and the amounts being claimed by each person, many people will hesitate to institute an individual action against the Defendants. Even if the Class Members themselves could afford such individual litigation, the court system could not as it would be overloaded and, at the very least, it is not in the interests of judicial economy. Furthermore, individual litigation of the factual and legal issues raised by the conduct of the Defendants would increase delay and expense to all parties and to the court system.

262. By their very nature, medical product liability cases affect many individuals and if it were not for the class action mechanism which facilitates access to justice, these types of claims may never be heard.

263. This class action overcomes the dilemma inherent in an individual action whereby the legal fees alone would deter recovery and thereby in empowering the consumer, it realizes both individual and social justice as well as rectifies the imbalance and restore the parties to parity.

264. Also, a multitude of actions instituted in different jurisdictions, both territorial (different provinces) and judicial districts (same province), risks having contradictory and inconsistent judgments on questions of fact and law that are similar or related to all members of the Class.

265. In these circumstances, a class action is the only appropriate procedure for all of the members of the Class to effectively pursue their respective legal rights and have access to justice.

266. The Plaintiff has the capacity and interest to fairly and fully protect and represent the interests of the proposed Class and has given the mandate to his counsel to obtain all relevant information with respect to the present action and intends to keep informed of all developments. In addition, class counsel is qualified to prosecute complex class actions.

LEGISLATION

267. The Plaintiff pleads and relies on the *Class Proceedings Act*, the *Courts of Justice Act*, the *Negligence Act*, the *Competition Act*, the *Food and Drugs Act*, the *Health Insurance Act*, and other legislation.

JURISDICTION AND FORUM

Real and Substantial Connection with Ontario

268. There is a real and substantial connection between the subject matter of this action and the province of Ontario because:

(a) Defendants Bard Canada Inc. and Genzyme Canada Inc. have their head offices in Ontario;

(b) The Defendants engage in business in Ontario;

(c) The Defendants derive substantial revenue from carrying on business in Ontario; and

~~(d)~~ The damages of Class Members were sustained in Ontario and in Canada.

269. The Plaintiff proposes that this action be tried in the City of Ottawa, in the Province of Ontario as a proceeding under the *Class Proceedings Act*.

DEFENDANTS' JOINT AND SEVERAL LIABILITY

270. The Plaintiff pleads that by virtue of the acts and omissions described above, the Defendants are liable in damages to himself and to the Class Members and that each Defendant is responsible for the acts and omissions of the other Defendants for the following reasons:

(a) Each was the agent of the other;

(b) Each companies' business was operated so that it was inextricably interwoven with the business of the other as set out above;

(c) Each company entered into a common advertising and business plan to research, develop, design, manufacture, test, produce, supply, market, label, package, promote, advertise, import, distribute, and/or sell the Hernia Mesh Devices;

(d) Each owed a duty of care to the other and to each Class Member by virtue of the common business plan to research, develop, design, manufacture, test, produce, supply, market, label, package, promote, advertise, import, distribute, and/or sell the Hernia Mesh Devices; and

(e) The Defendants intended that their businesses be run as one global business organization.

271. The Plaintiff and Class Members are entitled to legal and equitable relief against the Defendants, including damages, consequential damages, attorneys' fees, costs of suit and other relief as appropriate.

272. The Plaintiff and Class Members are entitled to recover damages and costs of administering the plan to distribute the recovery of the action.

SERVICE OUTSIDE ONTARIO

273. The originating process herein may be served on the foreign Defendants *ex juris* pursuant to subparagraphs (g), (h) and (p) of Rule 17.02 of the *Rules of Civil Procedure*. Specifically, the originating process herein may be served without court order outside Ontario, in that 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 wherever committed (rule 17.02(h));

(c) The claim is authorized by statute; including the *Competition Act* and the *Food and Drugs Act* (rule 17.02(n)); and

(d) Against a person carrying on business in Ontario (rule 17. 02(p)).

Date: April 28, 2017

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17-72462-CP

Court File No.

P[redacted] MCWILLIAMS
Plaintiff

BARD CANADA INC. *et alii.*
Defendants

ONTARIO
SUPERIOR COURT OF JUSTICE

PROCEEDING COMMENCED IN OTTAWA

Proceeding under the *Class Proceedings Act, 1992*

STATEMENT OF CLAIM

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