CANADA

PROVINCE OF QUEBEC
DISTRICT OF MONTREAL

NO: 500-06-000858-171

(Class Action)
SUPERIOR COURT

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**M. RENAUD**

*Petitioner*

-vs.-

**BARD CANADA INC.**, legal person duly constituted, having its head office at 2715 Bristol Circle #1, City of Oakville, Province of Ontario, L6H 6X5

and

**C.R. BARD, INC.**, legal person duly constituted, having its head office at 730 Central Avenue, City of New Providence, State of New Jersey, 07974, U.S.A.

and

**BARD ASDI, INC.**, legal person duly constituted, having its head office at 730 Central Avenue, City of New Providence, State of New Jersey, 07974, U.S.A.

and

**DAVOL INC.**, legal person duly constituted, having its head office at 100 Crossing Boulevard, City of Warwick, State of Rhode Island, 02886, U.S.A.

and

**GENZYME CANADA INC.**, legal person duly constituted, having its head office at 2700 Matheson Boulevard East, Suite 800, City of Mississauga, Province of Ontario, L5W 4V9

and

**GENZYME CORPORATION** also doing business as **GENZYME BIOSURGERY**, legal person duly constituted, having its head office at 500 Kendall Street, City of Cambridge, State of Massachusetts, 02142, U.S.A.

*Respondents*

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**APPLICATION TO AUTHORIZE THE BRINGING OF A CLASS ACTION & TO APPOINT THE PETITIONER AS REPRESENTATIVE PLAINTIFF (Art. 574 C.C.P and following)**

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TO ONE OF THE HONOURABLE JUSTICES OF THE SUPERIOR COURT, SITTING IN AND FOR THE DISTRICT OF MONTREAL, YOUR PETITIONER STATES AS FOLLOWS:

## I. GENERAL PRESENTATION

A) The Action

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

    - All persons residing in 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;

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

    (a) The Kugel Hernia Mesh Patch,

    (b) The 3DMax Mesh,

    (c) The PerFix Plug,

    (d) The Soft Mesh,

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

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

(f) The Sepramesh Composite;

3. The Hernia Mesh Devices are medical devices that are intended for surgical implantation in humans in order to repair hernias[2], by either patching the weakness in the abdominal wall or plugging the hole;

4. The Respondents researched, developed, designed, manufactured, tested, produced, supplied, marketed, labelled, packaged, promoted, advertised, imported, distributed, and/or sold the Hernia Mesh Devices as safe and/or effective despite a wealth of existing knowledge that the medical devices had dangerous and life-threatening complications including:

(a) Mesh erosion, contraction, and/or degradation,

(b) Infection, including sepsis[3] and gangrene (an infected hernia mesh almost always requires removal),

(c) 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),

(d) Perforation of bowel or other organs,

(e) Bowel obstruction (inability to defecate),

(f) Diarrhea (early symptom of the mesh attaching to the bowel),

(g) Constipation (sign of a bowel obstruction),

(h) Difficulty or inability to urinate,

(i) Chronic abdominal pain,

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

(k) Leg, groin, and testicular pain (often debilitating),

(l) Pain with sex (dyspareunia),

[2] As will be described in more detail herein, 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), incisional (resulting from an incision), femoral (outer groin), umbilical (belly button), and hiatal (upper stomach).

[3] Sepsis is the presence in tissues of harmful bacteria and their toxins, typically through infection of a wound.

(m) Rejection and foreign body response to the polypropylene,

(n) Amputation, including testicular removal,

(o) Slow healing wounds,

(p) Ulcers,

(q) Blood loss,

(r) Nausea (sign of adhesions to the bowel and/or stomach),

(s) Seroma[4],

(t) Fistulas[5],

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

(v) Autoimmune disorders,

(w) Neurological changes,

(x) Severe headaches,

(y) Fever (often associated with both an autoimmune response to the mesh and infection),

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

(aa) Liver abnormalities (associated with coated hernia meshes),

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

(cc) Abnormal perspiration (related to an autoimmune response or infection),

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

(ee) Chronic nerve damage,

[4] Seroma is a fluid capsule surrounding the mesh. Seromas can be present with and without infection.
[5] A fistula is an abnormal tunnel between two structures. Many fistulas connect to the bowel, which are associated with infections.

(ff) Chronic hernia-related pain,

(gg) Surgical correction/ implant revision surgery;

(hh) Permanent disability,

(ii) Physical pain and mental anguish,

(jj) Physical impairment and/or disfigurement, and/or

(kk) Death;

(hereinafter, the "Hernia Mesh Injuries" and/or the "Dangerous Complications");

5. In many cases, patients have been forced to undergo extensive medical treatment, including, but not limited to, operations to locate and remove the Hernia Mesh Devices, operations to attempt to repair hernias and/or recurrent hernias, tissue, and nerve damage, the use of pain control and other medications, injections and neuro-stimulators;

6. The Petitioner contends that the Respondents represented to the medical and healthcare community, to Health Canada, and to the Class Members that they had researched, developed, designed, manufactured, tested, produced, and supplied the Hernia Mesh Devices and that they had been found to be safe and/or effective for their intended use (i.e. surgical implantation for hernia repair), when they were not. In addition, the Respondents concealed their knowledge of the Hernia Mesh Devices' defects from the medical and healthcare community, Health Canada and from Class Members;

7. The overarching issues are that the Hernia Mesh Devices were developed, designed, manufactured, produced, and supplied with: (i) polypropylene, which 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, thereby leading to the Hernia Mesh Injuries (together the "Product Defects" and/or the "Design Defects");

8. In short, the Respondents' liability rests on their (i) failure to notify of the full scope of risks known to be associated with and caused by the Hernia Mesh Devices, (ii) safety misrepresentations, and (iii) inadequate warning about the risk of the Hernia Mesh Injuries;

9. The Respondents continue to market, label, package, promote, advertise, import, distribute, and/or sell the Hernia Mesh Devices throughout Canada, including within the province of Quebec, with inadequate warnings as to the serious and life-threatening Hernia Mesh Injuries;

B) The Respondents

10. Respondent 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 Respondent C.R. Bard, Inc. that does business throughout Canada, including within the province of Quebec, the whole as appears more fully from a copy of an extract from the Securities and Exchange Commission's website at www.sec.gov, a copy of an extract from Corporations Canada, and from a copy of Respondent Bard Canada's profile from the *Registraire des enterprises,* produced herein *en liasse* as **Exhibit R-1**;

11. Respondent 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 Respondents Bard Canada, Bard ASDI, Inc., and Davol, Inc. (Exhibit R-1). 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, the whole as appears more fully from a copy of the relevant extracts from Canadian Intellectual Property Office, produced herein *en liasse* as **Exhibit R-2**;

12. Respondent 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 Respondent C.R. Bard (Exhibit R-1). It is the owner of the patent "HERNIA MESH PATCH" ("PATCH EN FILET POUR LES HERNIES") (CA 2201439), which was filed on April 1, 1997, the whole as appears more fully from a copy of the patent documents, produced herein *en liasse* as **Exhibit R-3**;

13. Respondent 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 Respondent C.R. Bard, the whole as appears more fully from a copy of an extract from the Respondents' website at www.davol.com, produced herein as **Exhibit R-4**;

14. Respondent 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) "BARD SOFT MESH" (71895), which was first issued on July 19, 2006,

h) "BARD SOFT MESH PRE-SHAPED" (71895), which was first issued on July 19, 2006,

i) "BARD SOFT MESH PRE-SHAPED WITH SPERMATIC CORD", which was first issued on July 19, 2006,

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

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

l) The "BARD MODIFIED KUGEL HERNIA PATCH, CIRCLE" (65705), which was first issued on August 31, 2004,

m) "BIORESORBABLE COATING/PERMANENT MESH" (83022), which was first issued on July 6, 2011 and revoked on July 6, 2011, and

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

The whole as appears more fully from copies of the relevant licenses from Health Canada as well as a copy of a list of all of Respondent Davol’s manufactured active device licences, produced herein *en liasse* as **Exhibit R-5**;

15. Respondent 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 Quebec, the whole as appears more fully from a copy of Respondent Genzyme Canada’s profile from the *Registraire des enterprises,* produced herein as **Exhibit R-6**;

16. Respondent 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, the whole as appears more fully from a copy of the relevant extracts from Canadian Intellectual Property Office and from a copy of Respondent Genzyme’s Annual Report (Form 10-K) for the fiscal year ended December 31, 2006, produced herein *en liasse* as **Exhibit R-7**;

17. Respondent 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, the whole as appears more fully from a copy of the licenses from Health Canada, produced herein *en liasse* as **Exhibit R-8**;

18. On December 17, 2007, Respondent C.R. Bard entered into a license agreement with Respondent 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, the whole as appears more fully from a copy of Respondent C.R. Bard's Press Release entitled "Bard to License Hernia Product and Technology from Genzyme Corporation" dated December 17, 2007, produced herein as **Exhibit R-9**;

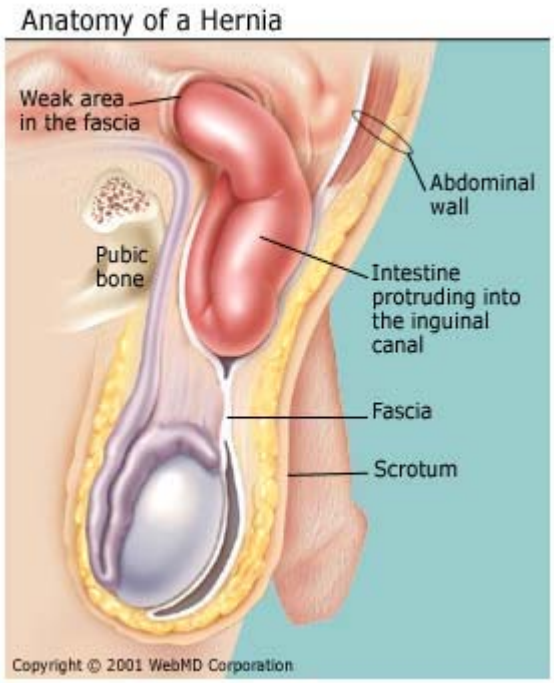
19. All Respondents have either directly or indirectly researched, developed, designed, manufactured, tested, produced, supplied, marketed, labelled, packaged, promoted, advertised, imported, distributed, and/or sold the Hernia Mesh Devices to distributors and retailers for resale to or, directly to physicians, hospitals, medical practitioners and to the general public throughout Canada, including within the province of Quebec;

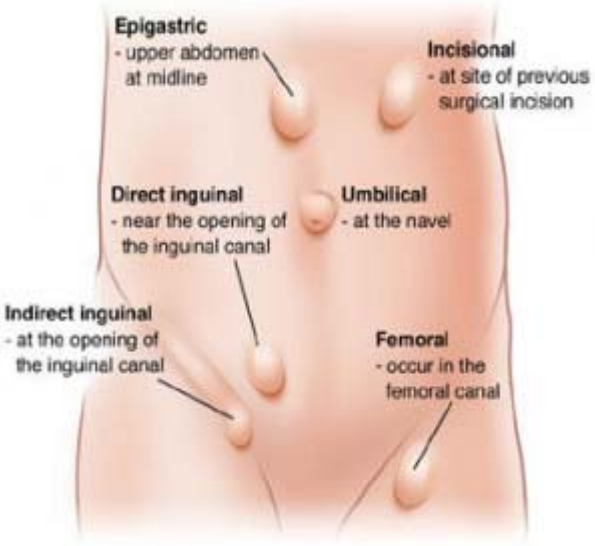
20. Given the close ties between the Respondents and considering the preceding, all Respondents are solidarily liable for the acts and omissions of the other;

C) <u>The Situation</u>

I. <u>Hernias – Explained</u>

21. 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);



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

23. 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, the whole as appears more fully from a copy of the Medscape article entitled "Open Inguinal Hernia Repair" dated August 9, 2016, produced herein as **Exhibit R-10**;

24. 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, the whole as appears more fully from a copy of an extract from the Ethicon website at www.herniasolutions.com, from a copy of an extract from the Respondents' website at www.crbard.com, and from a copy of the JAMA Surg. Article entitled "Trends in emergent hernia repair in the United States" dated March 1, 2015, produced herein *en liasse* as **Exhibit R-11**;

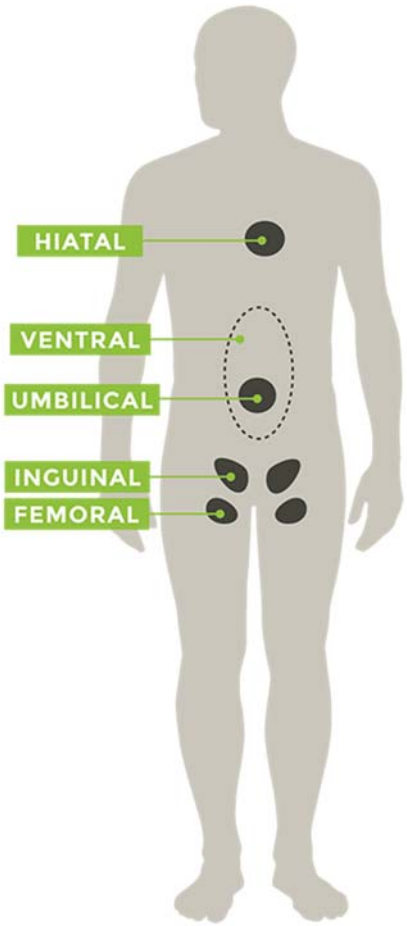
25. Inguinal hernias can be classified as either direct or indirect. An indirect inguinal hernia occurs through the natural weakness in the internal inguinal ring. A direct inguinal hernia is a result of weakness in the floor of the inguinal canal and is more likely to develop in older men over the age of 40. The floor of the inguinal canal is located just below the internal inguinal ring;

26. 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;

27. 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;

28. 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;

29. 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;




30. 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;

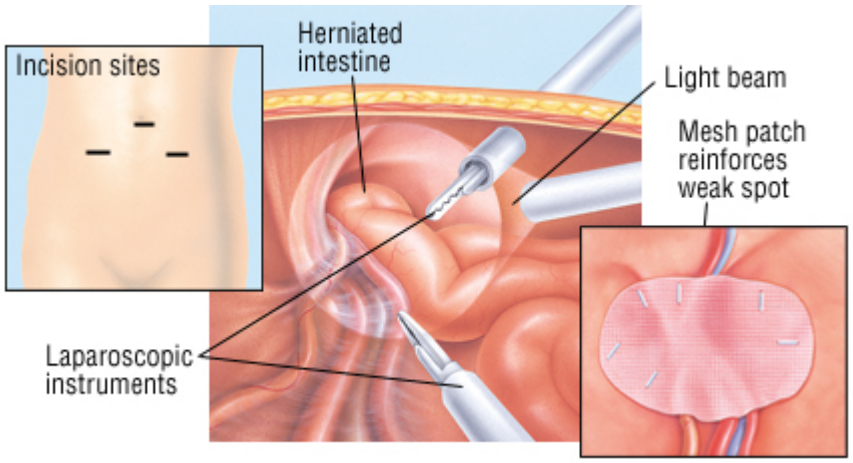
31. If left unattended, the weak spot can grow and simple acts like sneezing, coughing, laughing, bending over, or lifting heavy objects can be very painful;

II. Hernia Repair

32. 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 Application) (Exhibit R-10);

33. 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, the whole as appears more fully from a copy of the Annals of the Royal College of Surgeons of England article entitled "Which mesh for hernia repair" dated May 2010 and from a copy of the New England Journal of Medicine article entitled "A Comparison of Suture Repair with Mesh Repair for Incisional Hernia" dated August 10, 2000, produced herein *en liasse* as **Exhibit R-12**;

34. There are two types of surgeries for hernias – open and laparoscopic repairs. Laparoscopic hernia repair is similar to other laparoscopic procedures[6] 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 (Exhibit R-8), the whole as appears more fully from a copy of the Springer article entitled "Inguinal hernia repair, update 2006" dated 2006, produced herein as **Exhibit R-13**;

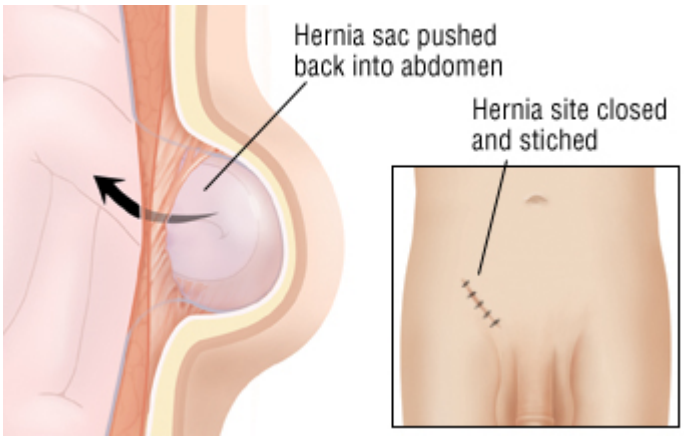



35. The majority of hernia repair surgeries today are performed laparoscopically and the Hernia Mesh Device is placed deeper into the abdominal cavity (intraperitoneally as opposed to preperitoneally[7]), meaning that the Hernia Mesh Device is placed directly on the organ, which increases the risk of adhesion thereto;

[6] 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.

[7] 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.

36. 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;




37. 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;

38. 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, the whole as appears more fully from a copy of an extract from the FDA website at www.fda.gov, produced herein as **Exhibit R-14**;

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

39. 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;

40. 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;

41. 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, (iii) the PerFix Plug, (iv) the Soft Mesh, and the (v) Ventralex Hernia Mesh and the coated mesh examples are: (vi) the Ventralex ST Hernia Mesh, and (vii) the Sepramesh IP Composite – all of which are made out of polypropylene, a synthetic plastic-like material that shrinks, erodes, and degrades over time, the whole as appears more fully from a copy of an extract from the Respondents' website at www.davol.com, produced herein as **Exhibit R-15**;

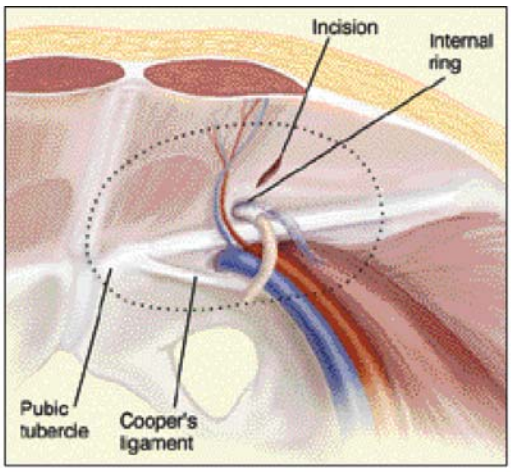
42. Due to the complications that polypropylene was causing when it came in direct contact with the human tissue, the demand for a coated (composite) hernia mesh skyrocketed. Any company with a composite mesh to sell could rapidly increase its nationwide market share. Mesh products were already one of 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;

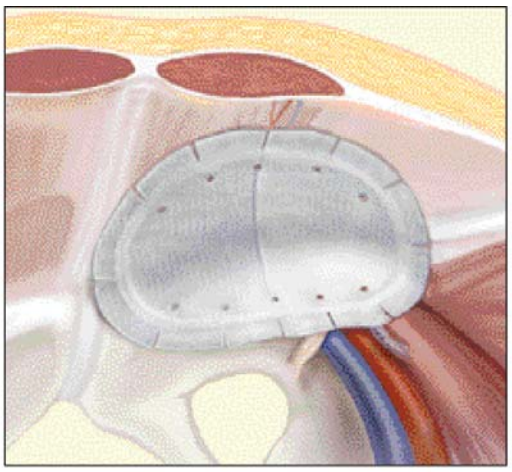
43. It is in this sense that the coated polypropylene mesh is a band-aid solution that caused an even bigger problem as it meant that patients were now being implanted with cheap plastic that degrades with highly allergenic properties on it;

44. Thus, the Respondents rushed to get a composite mesh on the market;

    (i) The Kugel Hernia Mesh Patch

45. 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;

46. The Kugel Hernia Patch is marketed by the Respondents as an "Open Posterior Approach to a Preperitoneal Inguinal Repair", the whole as appears more fully from a copy of an extract from the Respondents' website at www.davol.com, from a copy of the Respondents' Technique Guide, and from a copy of the Product Brochure, produced herein *en liasse* as **Exhibit R-16**;

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

48. 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;

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

50. 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."

The whole as appears more fully from a copy of the Health Canada Recalls and safety alerts listing for the Bard Composix Kugel Mesh X-Large Patch dated January 9, 2006, produced herein as **Exhibit R-17**;

51. 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;

52. 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 Respondents 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 Respondents continue to develop, design, manufacture, produce, supply, market, label, package, promote, advertise, import, distribute, and/or sell the Kugel Hernia Mesh Patches;

(ii) <u>The 3DMax Mesh</u>

53. 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;


54. The 3DMax Mesh is marketed by the Respondents as "A clinically proven fixation-free product for laparoscopic approaches such as TAPP, TEP, and Robotic TAPP"[8] and the Respondents claim that the "3DMAX mesh has been designed based on careful and precise anatomical research of the inguinal anatomy", the whole as appears more fully from a copy of an extract from the Respondents' website at www.davol.com, from a copy of the Respondents' Technique Guide, and from a copy of the Product Brochure, produced herein *en liasse* as **Exhibit R-18**;

55. 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;

56. 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

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

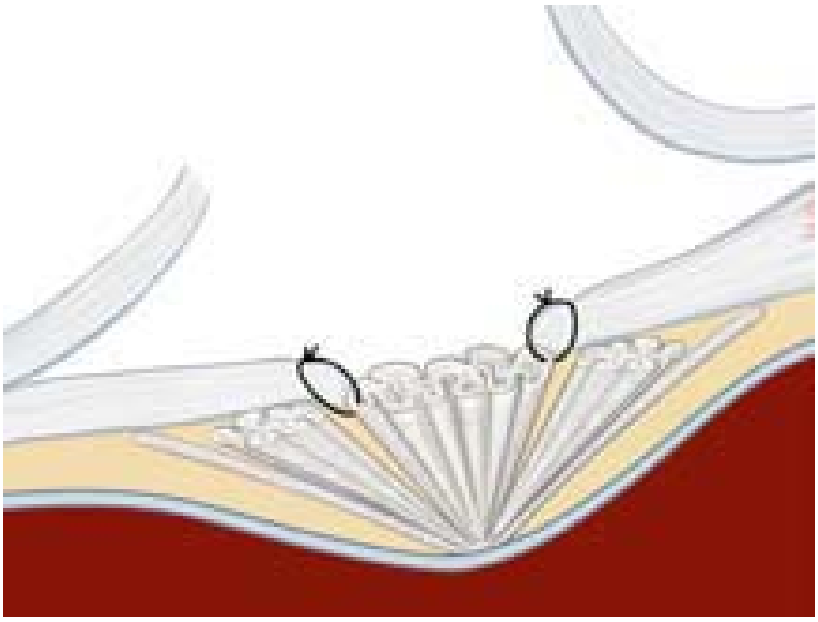
the 3DMax is so severe and debilitating that thousands of men have opted to have their testicle removed to alleviate the pain;

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

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

(iii) <u>The PerFix Plug</u>

59. 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;



60. The PerFix Plug is marketed by the Respondents 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”, the whole as appears more fully from a copy of an extract from the Respondents’ website at www.davol.com, from a copy of the Respondents’ Technique Guide, and from a copy of the Product Brochure, produced herein *en liasse* as **Exhibit R-19**;

61. 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;

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

63. 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;

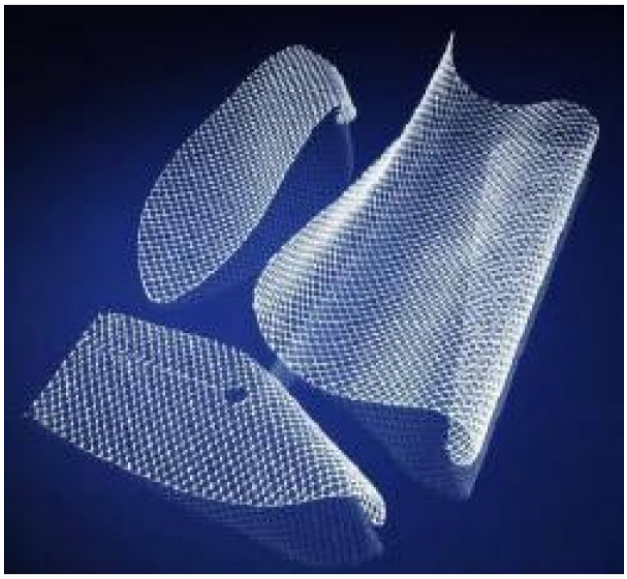
64. Like the 3DMax Mesh, the PerFix Plug must be removed before it erodes into the spermatic cord in men. Once the PerFix Plug has eroded into the spermatic cord, it could become impossible to remove without also removing a testicle;

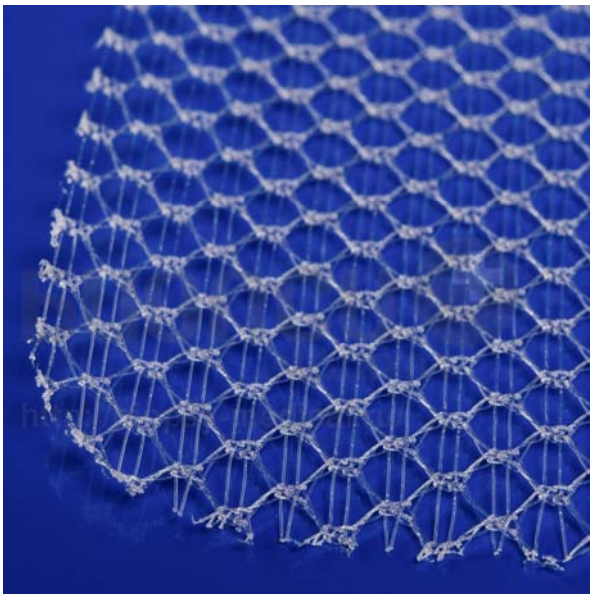
65. Many men are reporting severe, chronic groin and leg pain after being implanted with the PerFix Plug. The pain is so debilitating that numerous men report being unable to work or even walk;

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

(iv) The Soft Mesh

67. The Soft Mesh is a large pore monofilament polypropylene mesh used for hernia repair that is available either flat or pre-shaped.





68. The Soft Mesh is marketed by the Respondents as “lightweight”, with a “strong knit construction [that] can be easily tailored without lending itself to unraveling”, and which allows for “prompt fibroblastic tissue response”, the whole as appears more fully from a copy of an extract from the Respondents’ website at www.davol.com, from a copy of the Respondents’ Instructions for Use, and from a copy of the Product Brochure, produced herein *en liasse* as **Exhibit R-20**;

69. In addition to the major issue of it being made out of polypropylene, which shrinks and degrades over time, the woven design of the Soft Mesh with large pores (holes) causes nerves to grow into these pores and attach to the mesh soon after implant. The Respondents admit as much when they market it as providing a “prompt fibroblastic tissue response”, i.e. your nerves grow into it and incorporate it into your body. As the mesh erodes and migrates, it pulls

and stretches the nerves attached to it. The nerve stretching causes debilitating pain.

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

71. In addition, the Soft Mesh has been observed to become unwoven over time despite the Respondents' claims to the contrary. In many cases, the patient's body rejects small pieces of the unwoven Soft Mesh. This rejection process is slow and results in a chronic non-healing wound, which oftentimes leads to infections.

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

(v) <u>The Ventralex Hernia Mesh Patch and the Ventralex ST Hernia Mesh Patch</u>

73. 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;


74. The Ventralex ST Hernia Mesh Patch is marketed by the Respondents as "Efficient, Easy, Proven", the whole as appears more fully from a copy of an extract from the Respondents' website at <u>www.davol.com</u>, from a copy of the

Respondents' Technique Guide, and from a copy of the Product Brochure, produced herein *en liasse* as **Exhibit R-21**;

75. 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;

76. The Respondents promote the mesh coating as a "barrier" and instruct surgeons to use the coating as such. The US-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 Respondents simply informed the U.S. FDA that they would not promote their hernia mesh as a "barrier" medical device;

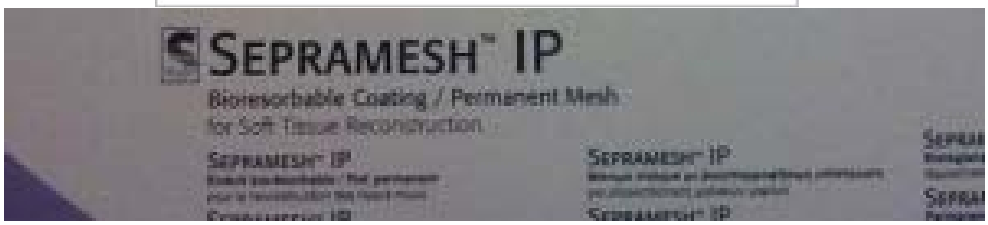
77. The Respondents based the design of the Ventralex ST Hernia Mesh Patch off of a prior Hernia Mesh Device design, the Kugel Hernia Mesh Patch [see section (i) above], several lots of which were recalled approximately a decade ago in the U.S. and Health Canada made one recall in Canada in 2006 (Exhibit R-17);

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

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

(vi) <u>The Sepramesh IP Composite</u>

80. The Sepramesh IP Composite is a polypropylene mesh with an absorbable carboxymethylcellulose-sodium hyaluronate 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;




81. 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;

82. The SepraMesh is marketed by the Respondents 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", the whole as appears more fully from a copy of an extract from the Respondents' website at www.davol.com, from a copy of the Respondents' Technique Guide, and from a copy of the Product Brochure, produced herein *en liasse* as **Exhibit R-22**;

83. The Sepramesh is built on "2 key components: sodium hyaluronate (HA) and carboxymethylcellulose (CMC)"; the same as the Seprafilm products (Exhibit R-22 – Brochure);

84. On December 20, 2013, Respondent 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."

The whole as appears more fully from a copy of the U.S. Department of Justice Press Release dated December 20, 2013, produced herein as **Exhibit R-23**;

85. On September 3, 2015, Respondent 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, the whole as appears more fully from a copy of the U.S. Department of Justice Press Release dated September 3, 2015, from a copy of the Deferred Prosecution Agreement dated August 31, 2015 (including its attachments), and from a copy of the Information, produced herein *en liasse* as **Exhibit R-24**;

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

IV. <u>Polypropylene – the Common Denominator</u>

87. 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 Respondents used this material in their design of the Hernia Mesh Devices;

88. 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

89. The Material Data Safety Sheet (MSDS) for Polypropylene states the following prohibited use: “Applications involving permanent implantation into the body”, the whole as appears more fully from a copy of the LyondellBasell safety data sheet for Polypropylene dated April 17, 2015, produced herein as **Exhibit R-25**;

90. 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;

91. The Respondents 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 actions in Canada over their transvaginal mesh and bladder sling products, which are also made from polypropylene. Despite the known risk associated with polypropylene, the Respondents continue to manufacture the Hernia Mesh Devices with it;

V. <u>The Scientific Studies</u>

92. 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;

93. 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 Respondents to redesign or to discontinue their products. Instead, those criticisms only caused Respondents to amplify their efforts to champion their product as will be elaborated hereinbelow;

94. However, the Respondents 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;

95. 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:

- 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, the whole as appears more fully from the study, produced herein as **Exhibit R-26**;

- J.W.A. Burger et al., "Evaluation of new prosthetic meshes for ventral hernia repair" (2006) 20 Surg Endosc 1320-1325, the whole as appears more fully from the study, produced herein as **Exhibit R-27**;

- 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), the whole as appears more fully from a copy of the abstract of the study, produced herein as **Exhibit R-28**;

- 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, the whole as appears more fully from the case report, produced herein as **Exhibit R-29**;

- 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, the whole as appears more fully from the study, produced herein as **Exhibit R-30**;

- 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, the whole as appears more fully from the study, produced herein as **Exhibit R-31**;

- Marc H. F. Schreinemacher et al., "Coated meshes for hernia repair provide comparable intraperitoneal adhesion prevention" (2013) 27 Surg

Endosc 4202-4209, the whole as appears more fully from the study, produced herein as **Exhibit R-32**;

- 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, the whole as appears more fully from the study, produced herein as **Exhibit R-33**;

- 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, the whole as appears more fully from a copy of the study, produced herein as **Exhibit R-34**;

- Vladimir V. Iakovlev, Scott A. Guelcher, & Robert Bendavid, “Degradation of polypropylene in vivo: A microscopic analysis of meshes explanted from patients” (2015) wileyonlinelibrary, the whole as appears more fully from the study, produced herein as **Exhibit R-35**;

- 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, the whole as appears more fully from the study, produced herein as **Exhibit R-36**;

- Odd Langbach et al., “Oral, intestinal, and skin bacteria in ventral hernia mesh implants” (2016) 8 Journal of Oral Microbiology 31854, the whole as appears more fully from the study, produced herein as **Exhibit R-37**;

96. The 2004 Gonzalez et al. study (Exhibit R-26), 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;

97. The 2006 J.W.A. Burger et al. study (Exhibit R-27), 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;

98. The 2009 German Jonas J study (Exhibit R-28), 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;

99. The 2011 F.E. Muysoms et al. study (Exhibit R-29), 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";

100. The 2012 Corey R. Deeken et al. study (Exhibit R-30), 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";

101. The 2013 M. Ditzel et al. study (Exhibit R-31), 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";

102. The 2013 March H.F. Schreinemacher et al. study (Exhibit R-32), 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;

103. The 2014 Mylan T. Nguyen study (Exhibit R-33), 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;

104. The 2014 Robert Bendavid et al. study (Exhibit R-34), 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;

105. The 2015 Vladimir V. Iakovlev et al. study (Exhibit R-35), 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";

106. The 2016 R.B. Baucom study (Exhibit R-36), 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;

107. The 2016 Odd Langbach et al. study (Exhibit R-37), in testing bacterial colonization of mesh implants in patients without clinical signs of infection tested patients with failed hernia meshes. 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;

108. 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;

109. It seems that the Respondents, in initially designing the Hernia Mesh Products with polypropylene ran into a problem – polypropylene is not suitable for permanent implantation into the human body because of its innate properties. The solution that they found was to coat the unacceptable material to prevent direct contact with human tissue. Unfortunately, this coating, while indeed preventing the formation of adhesions to the polypropylene, was found to be equally unacceptable in that the human body will reject it;

110. Despite these studies, the Respondents 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 Respondents' Marketing Practices

111. Despite the risks of serious adverse events, the Respondents aggressively promoted the Hernia Mesh Devices;

112. The Respondents 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 Respondents made these statements, they knew or should have known that the they were false and/or inaccurate;

113. Representatives of the Respondents 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 Respondents' representatives made these statements, they knew or should have known that they were false and/or inaccurate;

114. The Respondents 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;

115. The Respondents 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 Dangerous Complications;

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

117. The Respondents' 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;

118. 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 available feasible other alternative treatments for hernias, and competing medical devices;

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

120. Physicians relied upon the above representations and advertisements to the Petitioner'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 Respondents actively concealed the Dangerous Complications of the Hernia Mesh Devices;

121. The Petitioner 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

122. 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);

123. 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), the whole as appears more fully from a copy of an extract from the Shouldice Hospital website at www.shouldice.com, produced herein as **Exhibit R-38**;

124. For over 70 years, the Shouldice Hospital has maintained a success rate of 99.5% on primary inguinal hernia repairs (Exhibit R-38);

125. 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;

126. 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 (Exhibit R-38);

127. 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;

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

129. The Bassini Repair involves the suturing of 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;

130. The Desarda technique, presented in 2001, is an original hernia repair method using an undetached strip of external oblique aponeurosis[9]. The beneficial results of this technique are substantially similar to that of using a mesh, but without the Hernia Mesh Injuries, the whole as appears more fully from a copy of the World Journal of Surgery study entitled "Desarda Versus Lichtenstein Technique for Primary Inguinal Hernia Treatment: 3-Year Results of a Randomized Clinical Trial" dated March 3, 2012, produced herein as **Exhibit R-39**;

131. 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;

132. 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;

133. 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 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. <u>The Product Defects</u>

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

134. 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[10], 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,

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 tissue, 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,

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

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 tissue, 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 more traditional tissue repairs and/or other hernia repair procedures;

135. The Respondents have 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 Respondents' Liability

136. Despite the vast amount of evidence that the Hernia Mesh Devices cause the Hernia Mesh Injuries, the Respondents 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;

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

138. Despite a clear signal, the Respondents 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;

139. The Respondents 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 Petitioner, 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 Petitioner, 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 Petitioner, 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 Respondents 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 Petitioner and Class Members;

140. As a result of the Respondents' negligence, the *Régie de l'assurance maladie du Québec* has 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 *Health Insurance Act*, RSQ c A-29;

X. Summative Remarks

141. Despite the vast availability of knowledge clearly indicating that surgical implantation of the Hernia Mesh Devices is causally-related to Hernia Mesh Injuries, the Respondents 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;

142. The Respondents 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;

143. The Respondents ignored the association between the use of the Hernia Mesh Devices and the risk of Hernia Mesh Injuries;

144. The Respondents 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 Quebec;

145. The Respondents 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;

146. The Respondents 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 Quebec, with the Design Defect coupled with active misrepresentations about its safety;

147. 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;

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

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

150. The Respondents concealed material information regarding the truth about the existence and nature of the Design Defect from the medical and health community, Health Canada, the Petitioner, 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;

## II. FACTS GIVING RISE TO AN INDIVIDUAL ACTION BY THE PETITIONER

151. On October 11, 2005, Mrs. Renaud underwent an left region inguinal hernia repair surgery at the Centre hospitalier régional du Grand-Portage at 75 rue Saint-Henri, in Rivière-du-Loup, Quebec, during which time her hernia was operated upon using the Bassini Repair technique whereby her hernia was dissected, ligated, and reintroduced into the proper place (preperitoneally);

152. On December 16, 2010, Mrs. Renaud visited the Hôtel-Dieu de Québec at 11 Côte du Palais, in Quebec City, Quebec due to pain in her lower abdomen. Upon examination by echography, it was determined that there was a complication in her inguinal wall on the right-hand side and that a small

ganglion had formed[11] (the left-hand side having been determined to be have no significant abnormality);

153. On September 26, 2011, Mrs. Renaud underwent a second inguinal hernia repair surgery, this time for a right inguinal hernia at the Centre hospitalier universitaire de Québec at 775 rue Saint-Viateur, in Quebec City, Quebec. The surgery entailed the ligation of her epigastric vein and the cutting of her round ligament near its base at the internal inguinal orifice, which was also ligated. She did not have a hernial sac as such, but a curvature of the whole rear of the inguinal cavity. During this hernia repair surgery, she was surgically implanted with a Bard Soft Mesh to reinforce the repair area;

154. Mrs. Renaud 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 were safe;

155. On May 17, 2013, Mrs. Renaud again visited the Centre hospitalier universitaire de Québec at 775 rue Saint-Viateur, in Quebec City, Quebec as she was experiencing sensitivity and had the impression of feeling a mass in the region. An ultrasound was ordered by the physician to determine what the issue was;

156. On May 30, 2013, Mrs. Renaud had an ultrasound performed on her right inguinal area at the Hôtel-Dieu de Québec at 11 Côte du Palais, in Quebec City, Quebec to determine the cause of her pain. It was noted that there were several inguinal ganglia in her inguinal area;

157. An operation was scheduled to repair her femoral hernia as well as to verify the status of the right inguinal hernia;

158. On September 3, 2013, Mrs. Renaud underwent a third hernia repair operation at the Centre hospitalier universitaire de Québec at 775 rue Saint-Viateur, in Quebec City, Quebec. During this operation, it was determined that she had a right femoral hernia, which was reduced and a polytetrafluoroethylene (PTFE) prosthesis was used at the inguinal floor in order to terminate the femoral canal. In addition, a second hernia mesh product was used although it is uncertain at this point who the manufacturer is;

159. During this third hernia repair surgery, it was discovered that Mrs. Renaud's nerves and the Bard Soft Mesh had become intertwined and the surgeon therefore performed a neurectomy of her ilioinguinal nerve, i.e. her ilioinguinal nerve was removed. At that time, Mrs. Renaud was not aware that this procedure was related to any Design Defect of the Hernia Mesh Device;

[11] A ganglion cyst is a tumor or swelling on top of a joint or the covering of a tendon (tissue that connects muscle to bone). It looks like a sac of liquid (cyst). Inside the cyst is a thick, sticky, clear, colorless, jellylike material. Depending on the size, cysts may feel firm or spongy

160. Mrs. Renaud continued experiencing serious pain following the operation;

161. On February 20, 2014, Mrs. Renaud returned to the Hôtel-Dieu de Québec at 11 Côte du Palais, in Quebec City, Quebec to have ultrasound performed on her right inguinal area to determine the cause of her pain. It was noted that there were several inguinal ganglia in her inguinal area and that her hernias had recurred;

162. At no time was the Petitioner made aware of the risk of Hernia Mesh Injuries associated with the surgical implantation of the Hernia Mesh Devices;

163. The Petitioner has only recently become aware that the Hernia Mesh Devices suffered from a Design Defect whereby, when used as directed, they expose patients to the Dangerous Complications;

164. Had the Respondents properly disclosed the risks associated with the Hernia Mesh Devices, i.e. that they were defective, Mrs. Renaud would not have been exposed to the Dangerous Complications;

165. The Petitioner is aware that several lawsuits were filed in the United States due to the defects associated with the Hernia Mesh Devices and due to the Respondents' conduct related thereto, as appears more fully from a copy of the U.S. Complaints, produced herein *en liasse* as **Exhibit R-40**;

166. As a result of the Respondents' conduct, the Petitioner sustained and continues to suffer damages, including, but not limited to severe and chronic groin, blood loss, nausea, chronic physical pain, chronic nerve damages, surgical removal of her nerves, mental anguish, physical impairment, 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;

167. Petitioner's damages are a direct and proximate result of having been implanted with the Hernia Mesh Device, Respondents' negligence and/or lack of adequate warnings, wrongful conduct, and the unreasonably dangerous and defective characteristics of the Hernia Mesh Devices;

168. In consequence of the foregoing, the Petitioner is justified in claiming damages;

## III. FACTS GIVING RISE TO AN INDIVIDUAL ACTION BY EACH OF THE MEMBERS OF THE GROUP

169. Every member of the Class has been surgically implanted with a Hernia Mesh Device or is the successor, family member, assign, and/or dependant of a person who has been surgically implanted with a Hernia Mesh Device;

170. The Class Members' damages would not have occurred, but for the acts, omissions and/or negligence of the Respondents in failing to ensure that the Hernia Mesh Devices were safe for implantation, for failing to provide adequate warning of the risks associated with the implantation of the medical device in the human body, for misleading representations and for omitting to disclose important information to Class Members, to their physicians, and to Health Canada;

171. In consequence of the foregoing, each member of the Class is justified in claiming at least one or more of the following as damages:

a. At least one or more of the Hernia Mesh Injuries;

b. Physical and mental/emotional injuries, including pain, suffering, anxiety, fear, loss of quality and enjoyment of life, increased risk of mental problems, damage to and/or loss of reputation;

c. 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;

d. Loss of income and loss of future income; and

e. Punitive damages;

172. As a direct result of the Respondents' conduct, the users' family members and dependants have, had, and/or will suffer damages and loss including:

a. Out-of-pocket expenses, including debts accrued and/or paying or providing nursing, housekeeping and other services;

b. Loss of income and loss of future income; and

c. Loss of support, guidance, care, consortium, and companionship that they might reasonably have expected to receive if the injuries had not occurred;

173. All of these damages to the Class Members are a direct and proximate result of the implantation of the Hernia Mesh Devices and the Respondents' conduct, negligence and failure to adequately disclose necessary information and the risks associated with the medical device;

## IV. CONDITIONS REQUIRED TO INSTITUTE A CLASS ACTION

A) The composition of the Class makes it difficult or impracticable to apply the rules for mandates to sue on behalf of others or for consolidation of proceedings

174. The Petitioner is unaware of the specific number of persons who were implanted with a Hernia Mesh Device, which information is confidential; however, it is safe to estimate that it is in the tens of thousands;

175. Class Members are numerous and are scattered across the entire province;

176. In addition, given the costs and risks inherent in an action before the courts, many people will hesitate to institute an individual action against the Respondents. Even if the Class Members themselves could afford such individual litigation, it would place an unjustifiable burden on the courts. Furthermore, individual litigation of the factual and legal issues raised by the conduct of the Respondents would increase delay and expense to all parties and to the court system;

177. Also, a multitude of actions instituted in different jurisdictions, risks having contradictory judgments on questions of fact and law that are similar or related to all members of the Class;

178. These facts demonstrate that it would be impractical, if not impossible, to contact each and every member of the Class to obtain mandates and to join them in one action;

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

B) The claims of the members of the Class raise identical, similar or related issues of law or fact

180. Individual issues, if any, pale by comparison to the numerous common issues that are significant to the outcome of the litigation;

181. The damages sustained by the Class Members flow, in each instance, from a common nucleus of operative facts, namely, Respondents' misconduct;

182. The claims of the members raise identical, similar or related issues of fact or law, namely:

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

b) Did any of the Respondents 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 Respondents negligent and/or did they fail in their duty of safety and/or duty to warn/inform imposed upon them as researchers, developers, designers, researchers, manufacturers, testers, producers, suppliers, marketers, labellers, packagers, promotors, advertisers, distributers, and/or sellers of the Hernia Mesh Devices?

d) 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?

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

f) Did the Respondents fail to conduct, supervise and/or monitor clinical trials for the Hernia Mesh Devices?

g) Did the Respondents know or should have known about the risks associated with the use of the Hernia Mesh Devices?

h) Did the Respondents 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?

i) Did the Respondents engage in false advertising when it represented, through advertisements, promotions and other representations, that the Hernia Mesh Devices were safe or omitted to disclose material facts regarding the Hernia Mesh Devices' safety?

j) Were the members of the Class prejudiced by having the Hernia Mesh Devices implanted during their hernia repair surgeries instead of using other suitable repair techniques, which have similar benefits, but do not pose such an increased risk of developing the Hernia Mesh Injuries?

k) In the affirmative to any of the above questions, did the Respondents' conduct engage their solidary liability toward the members of the Class?

l) If the responsibility of the Respondents is established, what is the nature and the extent of damages and other remedies to which the members of the Class can claim from the Respondents?

m) Are members of the Class entitled to bodily, moral, and material damages?

n) Are the members of the Class entitled to recover as damages an amount equal to their economic losses?

o) Are the members of the Class entitled to recover as damages an amount to compensate them for their pain and suffering?

p) Are members of the Class entitled to aggravated or punitive damages?

183. The interests of justice favour that this motion be granted in accordance with its conclusions;

## V. NATURE OF THE ACTION AND CONCLUSIONS SOUGHT

184. The action that the Petitioner wishes to institute on behalf of the members of the Class is an action in damages, injunctive relief, and declaratory judgment;

185. The conclusions that the Petitioner wishes to introduce by way of a motion to institute proceedings are:

GRANT the class action of the Petitioner and each of the members of the Class;

DECLARE that the Defendants failed to provide adequate warnings with regard to the dangerous side effects of the Hernia Mesh Devices;

ORDER the Defendants to recall the Hernia Mesh Devices;

DECLARE the Defendants solidarily liable for the damages suffered by the Petitioner and each of the members of the Class;

RESERVE the right of each of the members of the Class to claim future damages related to the implantation of the Hernia Mesh Devices;

CONDEMN the Defendants to pay to each member of the Class a sum to be determined in compensation of the damages suffered, and ORDER collective recovery of these sums;

CONDEMN the Defendants to pay to each of the members of the Class, punitive damages, and ORDER collective recovery of these sums;

CONDEMN the Defendants to pay interest and additional indemnity on the above sums according to law from the date of service of the motion to authorize a class action;

ORDER the Defendants to deposit in the office of this Court the totality of the sums which forms part of the collective recovery, with interest and costs;

ORDER that the claims of individual Class Members be the object of collective liquidation if the proof permits and alternately, by individual liquidation;

CONDEMN the Defendants to bear the costs of the present action including expert and notice fees;

RENDER any other order that this Honourable Court shall determine and that is in the interest of the members of the Class;

A) <u>The Petitioner requests that he be attributed the status of representative of the Class</u>

186. Petitioner is a member of the Class;

187. Petitioner is ready and available to manage and direct the present action in the interest of the members of the Class that he wishes to represent and is determined to lead the present dossier until a final resolution of the matter, the whole for the benefit of the Class, as well as, to dedicate the time necessary for the present action before the Courts and the *Fonds d'aide aux actions collectives*, as the case may be, and to collaborate with her attorneys;

188. Petitioner has the capacity and interest to fairly, properly, and adequately protect and represent the interest of the members of the Class;

189. Petitioner has given the mandate to her attorneys to obtain all relevant information with respect to the present action and intends to keep informed of all developments;

190. Petitioner, with the assistance of her attorneys, is ready and available to dedicate the time necessary for this action and to collaborate with other members of the Class and to keep them informed;

191. Petitioner has given instructions to her attorneys to put information about this class action on its website and to collect the coordinates of those Class Members that wish to be kept informed and participate in any resolution of the present matter, the whole as will be shown at the hearing;

192. Petitioner is in good faith and has instituted this action for the sole goal of having her rights, as well as the rights of other Class Members, recognized and protected so that they may be compensated for the damages that they have suffered as a consequence of the Respondents' conduct;

193. Petitioner understands the nature of the action;

194. Petitioner's interests are not antagonistic to those of other members of the Class;

195. Petitioner is prepared to be examined out-of-court on her allegations (as may be authorized by the Court) and to be present for Court hearings, as may be required and necessary;

196. Petitioner has spent time researching this issue on the internet and meeting with her attorneys to prepare this file. In so doing, she is convinced that the problem is widespread;

B) <u>The Petitioner suggests that this class action be exercised before the Superior Court of Justice in the district of Montreal</u>

197. A great number of the members of the Class reside in the judicial district of Montreal and in the appeal district of Montreal;

198. The Petitioner's attorneys practice their profession in the judicial district of Montreal;

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

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

**GRANT** the present motion;

**AUTHORIZE** the bringing of a class action in the form of a motion to institute proceedings in damages, injunctive relief, and declaratory relief;

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

- All persons residing in 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;

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

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

b) Did any of the Respondents 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 Respondents negligent and/or did they fail in their duty of safety and/or duty to warn/inform imposed upon them as researchers, developers, designers, researchers, manufacturers, testers, producers, suppliers, marketers, labellers, packagers, promotors, advertisers, distributers, and/or sellers of the Hernia Mesh Devices?

d) 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?

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

f) Did the Respondents fail to conduct, supervise and/or monitor clinical trials for the Hernia Mesh Devices?

g) Did the Respondents know or should have known about the risks associated with the use of the Hernia Mesh Devices?

h) Did the Respondents 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?

i) Did the Respondents engage in false advertising when it represented, through advertisements, promotions and other representations, that the Hernia Mesh Devices were safe or omitted to disclose material facts regarding the Hernia Mesh Devices' safety?

j) Were the members of the Class prejudiced by having the Hernia Mesh Devices implanted during their hernia repair surgeries instead of using other suitable repair techniques, which have similar benefits, but do not pose such an increased risk of developing the Hernia Mesh Injuries?

k) In the affirmative to any of the above questions, did the Respondents' conduct engage their solidary liability toward the members of the Class?

l) If the responsibility of the Respondents is established, what is the nature and the extent of damages and other remedies to which the members of the Class can claim from the Respondents?

m) Are members of the Class entitled to bodily, moral, and material damages?

n) Are the members of the Class entitled to recover as damages an amount equal to their economic losses?

o) Are the members of the Class entitled to recover as damages an amount to compensate them for their pain and suffering?

p) Are members of the Class entitled to aggravated or punitive damages?

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

GRANT the class action of the Petitioner and each of the members of the Class;

DECLARE that the Defendants failed to provide adequate warnings with regard to the dangerous side effects of the Hernia Mesh Devices;

ORDER the Defendants to recall the Hernia Mesh Devices;

DECLARE the Defendants solidarily liable for the damages suffered by the Petitioner and each of the members of the Class;

RESERVE the right of each of the members of the Class to claim future damages related to the implantation of the Hernia Mesh Devices;

CONDEMN the Defendants to pay to each member of the Class a sum to be determined in compensation of the damages suffered, and ORDER collective recovery of these sums;

CONDEMN the Defendants to pay to each of the members of the Class, punitive damages, and ORDER collective recovery of these sums;

CONDEMN the Defendants to pay interest and additional indemnity on the above sums according to law from the date of service of the motion to authorize a class action;

ORDER the Defendants to deposit in the office of this Court the totality of the sums which forms part of the collective recovery, with interest and costs;

ORDER that the claims of individual Class Members be the object of collective liquidation if the proof permits and alternately, by individual liquidation;

CONDEMN the Defendants to bear the costs of the present action including expert and notice fees;

RENDER any other order that this Honourable Court shall determine and that is in the interest of the members of the Class;

**DECLARE** that all members of the Class that have not requested their exclusion, be bound by any judgment to be rendered on the class action to be instituted in the manner provided for by the law;

**FIX** the delay of exclusion at thirty (30) days from the date of the publication of the notice to the Class Members, date upon which the members of the Class that have not exercised their means of exclusion will be bound by any judgment to be rendered herein;

**ORDER** the publication of a notice to the members of the group in accordance with article 579 C.C.P. within sixty (60) days from the judgment to be rendered herein in La Presse, the Montreal Gazette, and Le Soleil;

**ORDER** that said notice be available on the Respondents' websites, Facebook page(s), and twitter accounts with a link stating "Notice to individuals who have undergone hernia surgery and their surgeons";

**RENDER** any other order that this Honourable Court shall determine and that is in the interest of the members of the Class;

**THE WHOLE** with costs, including all publication and dissemination fees.

Montreal, May 11, 2017

(s) Andrea Grass

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Per: Me Andrea Grass
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