CV-17-577976-00CP

Court File No.:

ONTARIO
SUPERIOR COURT OF JUSTICE

B E T W E E N :

COLLEEN BRUNELLE and WAYNE BOOTH

Plaintiffs

- and -

MEDTRONIC CANADA, MEDTRONIC PLC, COVIDIEN CANADA ULC, and SOFRADIUM PRODUCTION

Defendants

Proceeding under the *Class Proceedings Act, 1992*

STATEMENT OF CLAIM

TO THE DEFENDANTS

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the plaintiff. The claim made against you is set out in the following pages.

IF YOU WISH TO DEFEND THIS PROCEEDING, you or an Ontario lawyer acting for you must prepare a statement of defence in Form 18A prescribed by the Rules of Civil Procedure, serve it on the plaintiff's lawyer or, where the plaintiff does not have a lawyer, serve it on the plaintiff, and file it, with proof of service, in this court office, WITHIN TWENTY DAYS after this statement of claim is served on you, if you are served in Ontario.

If you are served in another province or territory of Canada or in the United States of America, the period for serving and filing your statement of defence is forty days. If you are served outside Canada and the United States of America, the period is sixty days.

Instead of serving and filing a statement of defence, you may serve and file a notice of intent to defend in Form 18B prescribed by the Rules of Civil Procedure. This will entitle you to ten more days within which to serve and file your statement of defence.

IF YOU FAIL TO DEFEND THIS PROCEEDING, JUDGMENT MAY BE GIVEN AGAINST YOU IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU. IF YOU WISH TO DEFEND THIS PROCEEDING BUT ARE UNABLE TO PAY LEGAL FEES, LEGAL AID MAY BE AVAILABLE TO YOU BY CONTACTING A LOCAL LEGAL AID OFFICE.

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

Date June 28, 2017 Issued by _____
Local registrar

Address of court office: 10th Floor
393 University Avenue
Toronto, Ontario

TO: MEDTRONIC CANADA

99 Hereford Street
Brampton, Ontario
L6Y 0R3

AND TO: MEDTRONIC PLC

20 Lower Hatch Street
Dublin 2, Ireland

AND TO: COVIDIEN CANADA ULC

3967 112th Avenue S.E.
Calgary, Alberta
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AND TO: SOFRADIUM PRODUCTION

116 Avenue Du Formans
Trevoux, France
01600

CLAIM

1. The Plaintiffs, Colleen Brunelle and Wayne Booth (the "Plaintiffs"), claim on behalf of themselves and others similarly situated in Canada:

(a) an Order certifying this proceeding as a class proceeding and appointing them as Representative Plaintiffs for the class(es), to be further defined on the motion for certification;

(b) a declaration that the Defendants were negligent in the design, development, testing, research, manufacture, licensing, labelling, warning, marketing, distribution, and sale of their Parietex Products and ProGrip Products (as defined in paragraphs 28 and 32, respectively);

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

(d) pecuniary and special damages in the amount of $500,000 for each person implanted with one of the Defendants' Parietex Products and/or ProGrip Products or as aggregated following a trial on the common issues;

(e) non-pecuniary damages in an amount to be assessed for each person who was implanted with one of the Defendants' Parietex Products and/or ProGrip Products;

(f) in the alternative to the claim for damages, an accounting or other such restitutionary remedy disgorging the revenues realized by the Defendants from the sales of their Parietex Products and ProGrip Products;

(g) damages pursuant to the *Family Law Act*, RSO 1990, c F.3 s.61 and similar legislation and common law in other provinces, where applicable, in the amount of $100,000 for each such plaintiff;

(h) punitive, aggravated, and exemplary damages in the amount of $20,000,000;

(i) the costs of distributing all monies received to class members;

(j) prejudgement interest in the amount of 10% compounded annually or as otherwise awarded by this Honourable Court;

(k) costs on a substantial indemnity basis, plus applicable taxes; and

(l) such further and other relief as this Honourable Court may deem just.

NATURE OF THE ACTION

2. This proposed class proceeding involves Parietex Products and ProGrip Products – surgical mesh products intended for the repair of hernias. This action arises out of the Defendants' unlawful, negligent, inadequate, improper, unfair, and deceptive practices and misrepresentations related to, *inter alia*, their design, development, testing, research, manufacture, licensing, labelling, warning, marketing, distribution, and sale of their Parietex Products and ProGrip Products.

3. The Defendants misrepresented that their Parietex Products and ProGrip Products are safe and effective, when in fact these devices cause serious Injuries, Conditions, and Complications (as defined in paragraph 36).

4. Patients implanted with the Defendants' Parietex Products and ProGrip Products were misled as to the devices' safety and efficacy, and as a result have suffered serious Injuries, Conditions, and Complications.

THE PLAINTIFFS

5. The Plaintiffs, Colleen Brunelle and Wayne Booth, reside in Fergus, Ontario.

6. In June of 2009, Ms. Brunelle was implanted with one of the Defendants' Parietex Products to surgically repair a ventral hernia.

7. Mr. Booth is the spouse of Ms. Brunelle, and is pursuing his claim in that capacity.

THE DEFENDANTS

8. The Defendant, Medtronic PLC, is a global medical technology company headquartered in Dublin, Ireland.

9. The Defendant, Medtronic Canada, in an Ontario Corporation headquartered in Brampton, Ontario.

10. The Defendant, Covidien Canada ULC, is an Alberta corporation, with its head office located in Calgary, Alberta. Covidien Canada ULC has a second office located in Quebec.

11. In January of 2015, Covidien PLC was acquired by Medtronic PLC. Covidien products, including Parietex Products and ProGrip Products, are marketed, distributed, and sold by Medtronic.

12. The Defendant, Sofradium Production, is a fully owned subsidiary of Medtronic PLC. Sofradium Production possess the necessary Medical Device Licence to market and sell Parietex Products and ProGrip Products in Canada.

13. Hereinafter, each of the above Defendants shall be collectively referred to as the "Defendants".

14. The business of each of the Defendants is inextricably interwoven with that of the other and each is the agent of the other for the purposes of researching, designing, manufacturing, developing, preparing, processing, inspecting, testing, packaging, promoting, marketing, distributing, labelling, and/or selling for a profit, either directly or indirectly through an agent, affiliate or subsidiary, Parietex Products and ProGrip Products in Canada. At all material times, the Defendants were engaged in the business of designing, manufacturing, testing, packaging, promoting, marketing, distributing, labelling, and/or selling Parietex Products and ProGrip Products in Canada. The development of Parietex Products and ProGrip Products for sale in Canada, the conduct of clinical studies, the preparation of regulatory applications, the maintenance of regulatory records, the labelling and promotional activities regarding Parietex Products and ProGrip Products, and other actions central to the allegations of this lawsuit, were undertaken by the Defendants in Ontario and elsewhere.

15. In bringing this action on behalf of all persons resident in Canada who were implanted with Parietex Products and/or ProGrip Products at any time on or before the date of the certification order, which was manufactured, marketed and/or sold or otherwise placed into the stream of commerce in Canada by one or more of the Defendants, the Plaintiffs plead and rely upon the provisions of the *Class Proceedings Act, 1992*, SO 1992, c6, the

Negligence Act, RSO 1990, c N-1, as amended and regulations thereunder, and the *Food and Drugs Act,* RSC 1985, c F.27 and regulations thereunder. The Plaintiffs also bring this action on behalf of all persons resident in Canada entitled to claim by virtue of a personal or familial relationship to any one or more of the persons described above, and plead and rely upon the Ontario *Family Law Act,* RSO 1990, C F.3 and regulations thereunder, and any analogous provincial legislation.

THE DEFENDANTS' HERNIA PRODUCTS

16. Parietex Products and ProGrip Products are designed for hernia repair. A hernia occurs when an organ pushes through an opening in the muscle or tissue that holds it in place. For example, the intestines may break through a weakened area in the abdominal wall. Hernias can occur in the abdomen (ventral hernias), the upper thigh (femoral hernias), belly button (umbilical hernias), and groin areas (inguinal hernias).

17. The use of a mesh in reconstruction of abdominal wall hernias is viewed by the medical community as an acceptable standard of care for hernia repair. Mesh is placed either under or over the defect in the abdominal wall and sutured in place. Mesh acts as "scaffolding" for new growth of a patient's own tissue, which eventually incorporates the mesh into the surrounding area.

18. Hernias can be surgically repaired using the conventional open method, which involves an incision to access the hernia, or the less invasive laparoscopic method. In laparoscopic repair, a few small incisions are made through the abdominal wall to insert the laparoscope (a thin telescope with a light on the end) and surgical instruments into the abdomen. The hernia is then viewed from inside the abdomen, from the other side of the abdominal wall. The abdominal cavity is inflated with carbon dioxide gas to give the

surgeon space to work inside the patient and the actual operating is done remotely with long instruments.

19. For laparoscopic hernia repairs, mesh must be suitable for intraperitoneal placement. Mesh adhesions, where the mesh rigidly attaches and integrates into the bowel or other viscera, are a frequently observed complication with intraperitoneal mesh placement. Accordingly, mesh materials have evolved to include "barrier" or "anti-adhesive" products, which include a permanent or absorbable coating which purports to minimize adhesion of the abdominal viscera to the mesh when placed intraperitoneally. Coated hernia products are intended to be easier to place during laparoscopic surgeries and may be placed close to the bowel.

THE DEFENDANTS' PARIETEX PRODUCTS

20. Covidien's Parietex™ products are created from a macroporous polyester material, specifically polyethylene terephthalate ("PET").

21. The Defendants' Parietex Products are indicated for both open and laparoscopic hernia repairs. Parietex Products, which are available in a variety of shapes and sizes, have evolved in design to compete in the medical device market.

22. The Parietex Products differ from hernia mesh products of other manufacturers as they are constructed from polyester, as opposed to an alternative non-absorbable polymer.

23. Parietex Mesh entered the Canadian market in 2006. Parietex mesh is a heavy weight multifilament polyester mesh.

24. Later in 2006, the Defendants' released Parietex Composite Mesh, a coated barrier mesh. This product is composed of a non-absorbable multifilament polyester mesh coated with

an absorbable collagen barrier on the visceral side. The collagen coating is intended to minimize adhesion formation between the mesh and the viscera upon implantation. After approximately three weeks, the collagen coating absorbs and the permeant polyester mesh remains in place.

25. In 2010, the Defendants introduced Parietex Lightweight Mesh, a monofilament polyester mesh. The Defendants claim that this lightweight product is "designed to provide patients the optimal clinical benefits of polyester in a strong, lightweight, monofilament knit for lasting comfort."

26. In 2012, the Defendants introduced Parietex Optimized Composite Mesh. This is a coated product similar to the Parietex Composite Mesh, which was held out to be more resistant to damage. The Parietex Optimized Composite Mesh was released after the Defendants received complaints that their Parietex Composite Mesh was prone to tearing.

27. In 2014, the Defendants introduced ProGrip Self-Griping Polyester Mesh.

28. The Defendants' products listed in paragraphs 20 – 27 above, are collectively referenced herein as "Parietex Products".

THE DEFENDANTS' PROGRIP PRODUCTS

29. In 2014, the Defendants introduced their self-gripping suture-less ProGrip Products to the Canadian market.

30. ProGrip Products are equipped with Velcro-like polylactic acid micro-hooks, which adhere to the surrounding tissue for a suture-less repair. No fixing device or glue is used. The polylactic acid micro-hooks are intended to absorb approximately 18 months after implantation.

31. The ProGrip Self-Gripping Polyester Mesh is a monofilament polyester mesh equipped with polylactic acid micro-hooks. When the micro-hooks absorb, the permanent polyester mesh is intended to remain in place.

32. The ProGrip Self-Gripping Polypropylene Mesh a monofilament polypropylene mesh equipped with polylactic acid micro-hooks. The permanent polypropylene mesh is intended to remain in place after the micro-hooks absorb.

33. The Defendants' products listed in paragraphs 29 – 32 above, are collectively referenced herein as "ProGrip Products".

34. The Defendants specifically market that their ProGrip Products result in "less pain" and "increases the security" of hernia repairs.

THE RISKS

35. The Defendants knew or ought to have known that their Parietex Products and ProGrip Products are defective, and are not properly manufactured to withstand normal, foreseeable, and intended use. The Defendants' Parietex Products and ProGrip Products have high failure, injury, and complication rates, fail to perform as intended, have resulted in severe and irreversible injuries, conditions, and have caused damage to the Representative Plaintiffs and other putative class members.

36. The Injuries, Conditions, and Complications suffered due to the Defendants' Parietex Products and ProGrip Products include, but are not limited to: hernia recurrence, chronic pain, mesh contraction, mesh migration, scarring, adhesions, infection, abscess formation, bleeding, intestinal blockage, fistulas, hematomas, seromas, perforations, allergic

reactions, rashes, and the need for further surgeries and procedures (collectively the "Injuries, Conditions, and Complications").

37. Notably, no human trials were conducted with the Parietex hernia mesh before it was sold.

38. The failures of Defendants' Parietex Products are attributable, in part, to the fact that all of the Defendants' Parietex Products suffer from a common design defect, the use of polyester material. Additionally, Parietex Products are designed with unsealed edges. The exposed individual polyester fibres frequently fray and unravel, weakening the integrity of the mesh.

39. After insertion of a synthetic material in the body, such as a hernia mesh, a foreign body response is systemically triggered by the immune system. However, the intensity and the chronicity of the foreign body response can be altered depending on the nature of the mesh material. In a study entitled *"Emerging Trends in Abdominal Wall Reinforcement: Bringing Bio-Functionality to Meshes"*, researchers noted that "uncontrolled foreign body response can lead to severe problems in hernia surgery (i.e. seroma formation, mesh shrinkage or encapsulation, tissue erosion and pain)."

40. Several studies have noted that when polyester is implanted in the body it invokes a severe foreign body response.

41. In a study entitled *"Comparative Analysis of Histopathologic effects of Synthetic Meshes Based on Material, Weight, and Pore Size in Mice"*, researchers concluded that "of the five synthetic meshes implanted, the polyester-based mesh was the greatest inducer of inflammation and appeared to impose a severe chronic foreign body reaction." The

researchers further noted that "material biocompatibility remains one of the most important determinants of mesh performance" and that polyester mesh was least biocompatible resulting in a "local hostile environment".

42. In a study entitled *"Polymers in hernia repair- common polyester vs. polypropylene surgical meshes"*, researchers noted "a significant increase in the rate of local inflammation" with the Parietex mesh as well as "wound edge separation." Further, Parietex mesh "developed the most extended stiffness of all tested materials, starting already 14 days after implantation."

43. In the same study, researchers observed fragmentation and degradation of the mesh *in vivo* after 90 days.

44. Researchers have also noted that polyester mesh is susceptible to substantial shrinkage after implantation. Since hernia mesh is intended to overlap the hernia defect, shrinkage weakens the integrity of the mesh increasing the risk of hernia recurrence.

45. In a study entitled *"Shrinkage of intraperitoneal onlay mesh in sheep: coated polyester mesh versus covered polypropylene mesh"*, researchers noted that the polyester-based mesh shrunk by 41% three months after implantation. Researchers speculate that it is the severe inflammatory response that is "the major cause of shrinkage."

46. The Defendants' more recent product changes, including the collagen coating and self-gripping micro-hooks, fail to mitigate the adverse effects of using polyester mesh.

47. For example, researchers have noted that when absorbable coatings are added to polyester mesh, "the coating may induce an excessive inflammatory reaction and, thus, a greater degree of shrinkage."

48. The failures of the Defendants' ProGrip Products are attributable, in part, to the fact that all of the Defendants' ProGrip Products suffer from a common design defect, the use of polylactic acid micro-hooks.

49. Despite the Defendants' statements that the ProGrip mesh is stronger and reduces pain, researchers have concluded that "the omission of mesh fixation with sutures and using the self-gripping ProGrip mesh did not reduce acute or chronic pain after operation" and observed a higher hernia recurrence rate associated with the product.

50. ProGrip Products are attached to the patient at thousands of different points. As the permanent mesh begins to shrink and contract, and the mesh pulls on all of the tissue and the nerves that it's attached to. Accordingly, the micro-grips themselves cause or contribute to patients developing significant pain and discomfort.

51. The Defendants' Parietex Products and ProGrip Products are inherently dangerous and defective, unfit and unsafe for their intended and reasonably foreseeable uses, and do not meet or perform to the expectations of patients and their health care providers.

52. At all material times, the Defendants knew or ought to have known that the risks of using their Parietex Products and ProGrip Products included severe Injuries, Conditions, and Complications.

53. The Defendants Parietex Products and ProGrip Products create risks to the health and safety of the patients that are far more significant than the risks posed by other products and procedures available to treat the corresponding medical conditions, and which far outweigh the utility of their Parietex Products and ProGrip Products.

54. At all material times, the Defendants, through their servants and agents, failed to adequately warn physicians and consumers, including the Plaintiffs and putative class members, of the risk of Injuries, Conditions, and Complications caused by their Parietex Products and/or ProGrip Products.

55. The Defendants did not provide adequate safety data to Health Canada with respect to their Parietex Products and ProGrip Products. The Defendants knew or ought to have known that their Parietex Products and ProGrip Products were unsafe, defective, unreasonably dangerous, and not fit for their intended purposes.

56. At all material times, the Defendants, through its servants and agents, negligently, recklessly and/or carelessly marketed, distributed and/or sold their Parietex Products and ProGrip Products without adequate warnings of the products' serious side effects and unreasonably dangerous risks.

THE PLAINTIFFS' EXPERIENCE

57. In June of 2009, Ms. Brunelle underwent a laparoscopic ventral hernia repair using the Defendants' Parietex Composite mesh at Guelph General Hospital. Ms. Burnelle did not suffer any surgical complications during implantation of the mesh.

58. After her surgery, Ms. Brunelle began to experience pain at her surgical site, which she describes as a "pinching" or "pulling" sensation.

59. In 2015, Ms. Brunelle's pain intensified and she began to see "bulging" on her abdomen. Ms. Burnelle was rushed by ambulance to the emergency department, where she became aware that her hernia had recurred and was strangulated. Ms. Brunelle underwent emergency surgery to repair the hernia.

60. Since her corrective surgery, Ms. Brunelle continues to experience pain and discomfort at her surgical site on a daily basis. Her pain increases in severity with activity and interferes with her ability to enjoy activities with her two children.

61. Ms. Brunelle has discussed her chronic pain with her doctors. She was advised that her only option to manage her symptoms was daily pain medication. Her doctor advised that further surgery could worsen her symptoms or result in additional complications.

62. Prior to and at the time when Ms. Burnelle was implanted with the Defendants' Parietex Product, she received no or inadequate warning about the risk of developing Injuries, Conditions, and Complications.

63. Had Ms. Burnelle been aware of the magnitude of risks of developing Injuries, Conditions, and Complications, she would never have agreed to being implanted with the Defendants' Parietex Product. But for the Defendants' wrongful conduct, the Plaintiffs would not have incurred damages.

64. The Plaintiff, Mr. Booth, and other class members, have suffered and continue to suffer damages including loss of care, guidance, companionship and consortium, as well as financial expenses and special damages due to the wrongful conduct of the Defendants.

CAUSES OF ACTION

65. The Defendants, at all material times, owed a duty of care to the Plaintiffs to:

(a) ensure that their Parietex Products and/or ProGrip Products were fit for their intended and/or reasonably foreseeable use;

(b) conduct appropriate testing to determine whether and to what extent use of their Parietex Products and/or ProGrip Products posed serious health risks, including the magnitude of risk of developing Injuries, Conditions, and Complications;

(c) properly, adequately, and fairly warn the Plaintiffs and physicians of the magnitude of the risk of developing Injuries, Conditions, and Complications with use of their Parietex Products and/or ProGrip Products compared to alternative treatments;

(d) ensure that physicians were kept fully and completely warned and informed regarding all risks associated with their Parietex Products and/or ProGrip Products;

(e) monitor, investigate, evaluate and follow up on adverse reactions to the use of their Parietex Products and/or ProGrip Products; and

(f) properly inform Health Canada and other regulatory agencies of all risks associated with their Parietex Products and/or ProGrip Products.

66. The Defendants negligently breached their duty of care.

67. The Plaintiffs state that their damages were caused by the negligence of the Defendants. Such negligence includes but is not limited to the following:

(a) the Defendants failed to ensure that their Parietex Products and/or ProGrip Products were not dangerous to recipients during the course of their use and that they were fit for their intended purpose and of merchantable quality;

(b) the Defendants failed to adequately test their Parietex Products and/or ProGrip Products in a manner that would fully disclose the magnitude of the risks associated with their use, including but not limited to Injuries, Conditions, and Complications;

(c) the Defendants unreasonably and carelessly designed products that were insufficient to withstand the foreseeable use of normal placement within the human body;

(d) the Defendants failed to provide Health Canada complete and accurate information with respect to their Parietex Products and/or ProGrip Products as it became available;

(e) the Defendants failed to conduct any or any adequate follow-up studies on the efficacy and safety of their Parietex Products and/or ProGrip Products;

(f) the Defendants failed to conduct any or any adequate long-term studies of the risks of their Parietex Products and/or ProGrip Products;

(g) the Defendants failed to provide the Plaintiffs, their physicians and Health Canada with proper, adequate, and/or fair warning of the risks associated with use of their

Parietex Products and/or ProGrip Products, including but not limited to risk of Injuries, Conditions, and Complications;

(h) the Defendants failed to warn or adequately warn the Plaintiffs or their physicians that in the event of failure, injury, or complications, it may be impossible to easily and safely remove the Defendants' Parietex Products and/or ProGrip Products, or to remove them at all;

(i) the Defendants failed to adequately monitor, evaluate and act upon reports of adverse reactions to their Parietex Products and/or ProGrip Products in Canada and elsewhere;

(j) the Defendants failed to provide any or any adequate updated and/or current information to the Plaintiffs, physicians and/or Health Canada respecting the risks of their Parietex Products and/or ProGrip Products as such information became available from time to time;

(k) the Defendants failed to provide adequate warnings of the risks associated with their Parietex Products and/or ProGrip Products, including the risk of Injuries, Conditions, and Complications in all persons receiving their Parietex Products and/or ProGrip Products on the patient information pamphlets in Canada;

(l) the Defendants, after noticing problems with their Parietex Products and/or ProGrip Products, failed to issue adequate warnings, timely recall their Parietex Products and/or ProGrip Products, publicize the problems and otherwise act properly and in a timely manner to alert the public, including adequately warning the Plaintiffs and their physicians of their Parietex Products' and/or ProGrip

Products' inherent dangers, including but not limited to the danger of Injuries, Conditions, and Complications;

(m) the Defendants failed to establish any adequate procedures to educate their sales representatives and physicians respecting the risks associated with their Parietex Products and/or ProGrip Products;

(n) the Defendants represented that their Parietex Products and/or ProGrip Products were safe and fit for their intended purpose and of merchantable quality when they knew or ought to have known that these representations were false;

(o) the Defendants misrepresented the state of research, opinion and medical literature pertaining to the purported benefits of their Parietex Products and/or ProGrip Products and their associated risks, including the risk of Injuries, Conditions, and Complications;

(p) the misrepresentations made by the Defendants were unreasonable in the face of the risks that were known or ought to have been known by the Defendants;

(q) the Defendants failed to timely cease the manufacture, marketing and/or distribution of their Parietex Products and/or ProGrip Products when they knew or ought to have known that their Parietex Products and/or ProGrip Products caused Injuries, Conditions, and Complications;

(r) the Defendants failed to conform with applicable disclosure and reporting requirements pursuant to the *Food and Drugs Act* and its associated regulations;

(s) the Defendants failed to properly supervise their employees, subsidiaries and affiliated corporations;

(t) the Defendants breached other duties of care to the Plaintiffs and putative class members, details of which breaches are known only to the Defendants; and

(u) in all of the circumstances of this case, the Defendants applied callous and reckless disregard for the health and safety of the Plaintiffs and putative class members.

68. The Defendants' Parietex Products and ProGrip Products are defective because they are unreasonably dangerous, beyond the dangers which could reasonably have been contemplated by the Plaintiffs, putative class members, or their physicians. Any benefit from using the Defendants' Parietex Products and ProGrip Products is outweighed by the serious and undisclosed risks of their use when used as the Defendants intended. There are no individuals for whom the benefits of the Defendants' Parietex Products and ProGrip Products outweigh the risks, given that there are many alternative products and procedures that are at least as efficacious as the Defendants' Parietex Products and ProGrip Products and carry far less and/or less serious risks than the Parietex Products and ProGrip Products.

69. The risks associated with use of the Defendants' Parietex Products and ProGrip Products, including Injuries, Conditions, and Complications in all persons receiving their Parietex Products and ProGrip Products, were in the exclusive knowledge and control of the Defendants. The extent of the risks were not known to, and could not have been known by, the Plaintiffs. The Plaintiffs' injuries would not have occurred but for the negligence

of the Defendants in failing to ensure that their Parietex Products and ProGrip Products were safe for use or, in the alternative, for failing to provide an adequate warning of the risks associated with using their Parietex Products and ProGrip Products to the Plaintiffs and putative class members, and to their physicians.

DAMAGES

70. The Plaintiffs' and other putative class members' injuries and damages were caused by the negligence of the Defendants, their servants and agents.

71. As a result of the Defendants' negligence, the Plaintiff has suffered and continues to experience serious personal injuries and harm with resultant pain and suffering. The Plaintiff will require additional surgeries and procedures.

72. The Plaintiff and other putative class members have suffered special damages for medical costs incurred in the screening, diagnosis, and treatment of Injuries, Conditions, and Complications related to use of the Defendants' Parietex Products and ProGrip Products.

73. As a result of the conduct of the Defendants, the Plaintiffs and other putative class members suffered and continue to suffer expenses and special damages, of a nature and amount to be particularized prior to trial.

74. Some of the expenses related to the medical treatment that the Plaintiff and class members have undergone, and will continue to undergo, have been borne by the various provincial health insurers.

75. The Plaintiffs claim punitive, aggravated, and exemplary damages for the reckless and unlawful conduct of the Defendants.

SERVICE OUTSIDE OF ONTARIO

76. The Plaintiffs plead and rely on sections 17.02 (g) and (p) of the Rules of Civil Procedure, allowing for service *ex juris* of the foreign defendants. Specifically, this originating process may be served without court order outside Ontario in that the claim is:

(a) in respect of a tort committed in Ontario (rule 17.02(g));

(b) against a person carrying on business in Ontario (rule 17.02(p)).

June 28, 2017

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Colleen Brunelle et al v. Covidien Canada ULC et al

CV 17 577976 00CP
Court File No.:

ONTARIO
SUPERIOR COURT OF JUSTICE

Proceeding commenced at Toronto
Proceeding under the *Class Proceedings Act, 1992*

STATEMENT OF CLAIM

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