Court File No.: CV-17-578509-00CP

ONTARIO
SUPERIOR COURT OF JUSTICE

B E T W E E N :

CHARLENE WEBER and TERRY WEBER

Plaintiffs

- and -

ATRIUM MEDICAL CORPORATION, MAQUET CARDIOVASCULAR, LLC, and GETINGE GROUP (aka GETINGE AB)

Defendants

Proceeding under the *Class Proceedings Act, 1992*

AMENDED 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 July 7, 2017

Issued by "N. MOHAMED"
Local registrar

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

TO: **Atrium Medical Corporation**

40 Continental Blvd.
Merrimack, NH,
US, 03054

AND TO: **Maquet Cardiovascular, LLC**

45 Barbour Pond Drive,
Wayne, New Jersey.
07470

AND TO: **Getinge Group (aka Getinge AB)**

Theres Svenssons gata 7,
P.O. Box 8861,SE- 402 72,
Göteborg, Sweden

CLAIM

1. The Plaintiffs, Charlene Weber and Terry Weber (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 C-QUR Mesh Products (as defined in paragraphs 19-20);

(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' C-QUR Mesh 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' C-QUR Mesh 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 C-QUR Mesh 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 C-QUR Mesh Products – C-QUR Mesh is a surgical mesh that is intended to repair abdominal wall 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 C-QUR Mesh Products.

3. The Defendants misrepresented that their C-QUR Mesh Products are safe and effective, when in fact these devices cause serious Injuries, Conditions, and Complications (as defined in paragraph 24).

4. Patients implanted with the Defendants' C-QUR Mesh 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, Charlene Weber and Terry Weber, reside in St. Thomas, Ontario.

6. In August of 2010, Ms. Weber was implanted with one of the Defendants' C-QUR Mesh Products to surgically repair a ventral hernia.

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

THE DEFENDANTS

8. The Defendant, Atrium Medical Corporation, is a Delaware corporation, headquartered in Merrimack, New Hampshire.

9. In 2011, Atrium Medical Corporation announced that it had signed an agreement to be acquired by Maquet Cardiovascular, a subsidiary of the Getinge Group (aka Getinge AB).

10. The Defendant, Getinge Group (aka Getinge AB), is a Swedish corporation headquartered in Göteborg.

11. The Defendant, Maquet Cardiovascular, LLC, is a Delaware corporation, headquartered in Wayne, New Jersey.

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

13. 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, C-QUR Mesh 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 C-QUR Mesh Products in Canada. The development of C-QUR Mesh 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 C-QUR Mesh Products, and other actions central to the allegations of this lawsuit, were undertaken by the Defendants in Ontario and elsewhere.

14. In bringing this action on behalf of all persons resident in Canada who were implanted with C-QUR Mesh 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' C-QUR MESH PRODUCTS

15. C-QUR Mesh is an implantable flat surgical mesh designed for hernia repair and other soft tissue deficiencies. 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 may occur in the abdomen (ventral hernias), the upper thigh (femoral hernias), belly button (umbilical hernias), and groin areas (inguinal hernias).

16. 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.

17. Hernias can be surgically repaired using the conventional open method, 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.

18. 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, is a frequently observed complication with intraperitoneal mesh placement. Accordingly, mesh materials evolved to include "barrier" or "anti-adhesive" products,

which include a permanent or absorbable barrier layer to minimize adhesion of the abdominal viscera to the mesh when placed intraperitoneally.

19. C-QUR Mesh is a non-absorbable polypropylene mesh coated with a bioabsorbable oil coating, comprised from pharmaceutical grade fish oil and a unique blend of triglycerides, omega 3 fatty acids, and other substances. The purported purpose of the bioabsorbable oil coating is to minimize adhesion formation between the mesh and the viscera upon implantation, and absorbs after surgical implantation. The permanent polypropylene mesh component is constructed of knitted filaments to facilitate tissue integration into the mesh pores.

20. Multiple models of C-QUR Mesh Products are available in a variety of shapes and sizes, under the Health Canada Medical Device Licence Number 72414, collectively referenced as "C-QUR Mesh Products" herein.

21. C-QUR Mesh Products first became available in the US in March of 2006. The Defendants sought approval of C-QUR Mesh Products through a special process—the 510(k) process—to avoid pre-market regulatory scrutiny of its devices. Pursuant to the 510(k) process, the Defendants attested that their C-QUR Mesh Products were "substantially equivalent" to other hernia mesh products, and were not required to submit rigorous clinical trial data to prove C-QUR Mesh Products were safe and effective. However, Atrium's C-QUR hernia mesh is the first mesh to ever utilize an omega 3 fatty acid coating.

22. Shortly after US approval, Health Canada approved C-QUR Mesh Products for sale in Canada in September of 2006.

THE RISKS

23. The Defendants knew or ought to have known that their C-QUR Mesh Products are defective, and are not properly manufactured to withstand normal, foreseeable, and intended use. The Defendants' C-QUR Mesh 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.

24. The Injuries, Conditions, and Complications suffered due to the Defendants' C-QUR Mesh 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 (collectively the "Injuries, Conditions, and Complications").

25. The failure of Defendants' C-QUR Mesh Products is attributable, in part, to the fact that all of the Defendants' C-QUR Mesh Products suffer from a common design defect, the bioabsorbable oil coating.

26. Researchers have compared the Defendants' C-QUR Mesh Products to other meshes on the market and found that C-QUR Mesh Products cause significant complications.

27. Case reports have described individuals experiencing painful foreign body reactions to the C-QUR Mesh, requiring removal of the mesh and surrounding affected tissues. In a 2012 study entitled "*A Review of the Composition, Characteristics, and Effectiveness of Barrier Mesh Prostheses Utilized for Laparoscopic Ventral Hernia Repair*", researchers

concluded that it is likely the bioabsorbable barrier of the C-QUR mesh that causes a wide range of inflammatory responses, resulting in dense adhesions.

28. The C-QUR mesh fails to properly integrate into host tissues after implantation. In a 2013 study entitled "*Coated Mesh for Hernia Repair Provide Comparable Intraperitoneal Adhesion Prevention*", researchers found that in comparison to other coated hernia mesh products, the Q-CUR mesh showed the weakest tissue integration. This finding is supported by a 2014 study entitled "*In Vivo Comparison of Marketed Biologically Augmented Hernia Grafts*", where researchers concluded that in comparison to other hernia mesh products, C-QUR mesh does not adequately support fibrovascular ingrowth. Without proper integration, the C-QUR mesh is at risk for migration or folding after implantation.

29. The C-QUR mesh has also been reported to tear after implantation. In a 2011 study, researchers observed that the C-QUR mesh exhibited decreased strength when compared to other hernia mesh products.

30. The Q-CUR mesh is highly susceptible to infection. A 2013 study entitled "*Case-control Study of Mesh-infection after a Size Tailored Hernia Repair with C-QUR V-Patch*" was stopped prematurely because of an unacceptably high rate of C-QUR hernia mesh infections. C-QUR's high infection rate has also been noted in animal studies; in a 2012 rat study entitled "*Experimental study on Synthetic and Biological Mesh Implantation in a Contaminated Environment*", researchers observed more infections associated with the C-QUR mesh than infections associated with all of the other brands of mesh included in the study combined.

31. The Defendants' C-QUR Mesh 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.

32. At all material times, the Defendants knew or ought to have known that the risks of using their C-QUR Mesh Products included severe Injuries, Conditions, and Complications.

33. The Defendants C-QUR Mesh 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 C-QUR Mesh Products.

34. 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 C-QUR Mesh Products.

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

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

THE PLAINTIFFS' EXPERIENCE

37. In August of 2010, Ms. Weber underwent a hernia repair using one of the Defendants' C-QUR Mesh Products at St. Thomas Elgin General Hospital. Ms. Weber did not suffer any surgical complications during implantation of the mesh.

38. Immediately following her surgery, Ms. Weber began to experience abdominal pain and cramping. About a year after her surgery, Ms. Weber's pain was not improving and had intensified. She also began to experience abdominal swelling and numbness as well as bowel and digestive complications that she did not experience prior to her surgery.

39. Concerned that "something wasn't right", Ms. Weber sought specialized medical attention. She was assessed by surgical specialists at the Shouldice Hospital in Toronto, a facility that specializes in hernia repair. Ms. Weber was advised that her hernia had recurred as the mesh had failed.

40. Ms. Weber was subsequently advised by her surgeon at St. Thomas Elgin General Hospital that she had developed a new lateral ventral hernia.

41. Ms. Weber was advised that she will require corrective surgery to remove the Defendants' mesh and repair the hernia again.

42. Ms. Weber continues to experience pain and discomfort on a daily basis. She manages her pain with reduced activity and over the counter pain medications.

43. Ms. Weber's pain and movement limitations interfere with her ability to perform her employment duties which include commercial cleaning, and detailing at Disbrowe Chevrolet Buick GMC Cadillac Ltd. Accordingly, she is strongly considering cutting back from full time to part time work.

44. Prior to and at the time when Ms. Weber was implanted with the Defendants' C-QUR Mesh Product, she received no or inadequate warning about the risk of developing Injuries, Conditions, and Complications.

45. Had Ms. Weber been aware of the magnitude of risks of developing Injuries, Conditions, and Complications, she would never have agreed to being implanted with the Defendants' C-QUR Mesh Product. But for the Defendants' wrongful conduct, the Plaintiffs would not have incurred damages.

46. The Plaintiff, Mr. Weber, 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

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

(a) ensure that their C-QUR Mesh 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 C-QUR Mesh 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 C-QUR Mesh Products compared to alternative treatments;

(d) ensure that physicians were kept fully and completely warned and informed regarding all risks associated with their C-QUR Mesh Products;

(e) monitor, investigate, evaluate and follow up on adverse reactions to the use of their C-QUR Mesh Products ; and

(f) properly inform Health Canada and other regulatory agencies of all risks associated with their C-QUR Mesh Products.

48. The Defendants negligently breached their duty of care.

49. 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 C-QUR Mesh 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 C-QUR Mesh 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 C-QUR Mesh 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 C-QUR Mesh Products;

(f) the Defendants failed to conduct any or any adequate long-term studies of the risks of their C-QUR Mesh 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 C-QUR Mesh 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' C-QUR Mesh Products , or to remove them at all;

(i) the Defendants failed to adequately monitor, evaluate and act upon reports of adverse reactions to their C-QUR Mesh 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 C-QUR Mesh Products as such information became available from time to time;

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

(l) the Defendants, after noticing problems with their C-QUR Mesh Products, failed to issue adequate warnings, timely recall their C-QUR Mesh 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 C-QUR Mesh 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 C-QUR Mesh Products;

(n) the Defendants represented that their C-QUR Mesh 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 C-QUR Mesh 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 C-QUR Mesh Products when they knew or ought to have known that their C-QUR Mesh 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.

50. The Defendants' C-QUR Mesh Products were 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' C-QUR Mesh Products was 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' C-QUR Mesh Products outweigh the risks, given that there are many alternative products and procedures that are at least as efficacious as the Defendants' C-QUR Mesh Products and carry far less and/or less serious risks than the C-QUR Mesh Products.

51. The risks associated with use of the Defendants' C-QUR Mesh Products, including Injuries, Conditions, and Complications in all persons receiving their C-QUR Mesh 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 C-QUR Mesh Products were safe for use or, in the alternative, for failing to provide an adequate warning of the risks associated with using their C-QUR Mesh Products to the Plaintiffs and putative class members, and to their physicians.

DAMAGES

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

53. 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.

54. The Plaintiffs 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' C-QUR Mesh Products.

55. 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.

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

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

SERVICE OUTSIDE OF ONTARIO

58. 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)).

July 7, 2017

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ONTARIO
SUPERIOR COURT OF JUSTICE

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

AMENDED STATEMENT OF CLAIM

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