Court File No. VLC-S-S-242613

No._____
Vancouver Registry

In the Supreme Court of British Columbia

Between

SHIRLEY ANTONELLI

Plaintiff

and

BARD CANADA INC., BECTON, DICKINSON AND COMPANY, C.R. BARD INC., BARD ACCESS SYSTEMS, INC., BARD PERIPHERAL VASCULAR, INC., AND BECTON DICKINSON CANADA INC.

Defendants

Brought under the *Class Proceedings Act*, RSBC 1996, c 50

NOTICE OF CIVIL CLAIM

This action has been started by the plaintiff for the relief set out in Part 2 below.

If you intend to respond to this action, you or your lawyer must

(a) file a response to civil claim in Form 2 in the above-named registry of this court within the time for response to civil claim described below, and

(b) serve a copy of the filed response to civil claim on the plaintiff.

If you intend to make a counterclaim, you or your lawyer must

(a) file a response to civil claim in Form 2 and a counterclaim in Form 3 in the above-named registry of this court within the time for response to civil claim described below, and

(b) serve a copy of the filed response to civil claim and counterclaim on the plaintiff and on any new parties named in the counterclaim.

JUDGMENT MAY BE PRONOUNCED AGAINST YOU IF YOU FAIL to file the response to civil claim within the time for response to civil claim described below.

Time for response to civil claim

A response to civil claim must be filed and served on the plaintiff,

(a) if you were served with the notice of civil claim anywhere in Canada, within 21 days after that service,

(b) if you were served with the notice of civil claim anywhere in the United States of America, within 35 days after that service,

(c) if you were served with the notice of civil claim anywhere else, within 49 days after that service, or

(d) if the time for response to civil claim has been set by order of the court, within that time.

CLAIM OF THE PLAINTIFF

PART 1: STATEMENT OF FACTS

Nature of the Action

1. This proposed class proceeding involves Implanted Catheter Products (as defined herein), which are medical devices that are often implanted in or near the chest to provide long-term access to major veins to allow for repeated drawing and/or delivery of fluids, medications, and/or nutrients. Each of the Defendants' Implanted Catheter Products includes a catheter component, which is comprised of a polymeric mixture that includes barium sulfate. 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 Implanted Catheter Products.

2. The Defendants misrepresented that their Implanted Catheter Products are safe and effective, when in fact these devices cause serious Injuries, Conditions, and Complications (as defined herein).

3. Patients who were implanted with the Defendants' Implanted Catheter Products were mislead to the devices' safety and efficacy and, as a result, have suffered serious Injuries, Conditions, and Complications.

The Parties

The Plaintiff

4. The Plaintiff, Shirley Antonelli (the "Plaintiff"), resides in Cole Harbour, British Columbia ("BC") and is 47 years old.

5. From approximately 2021 until 2023, the Plaintiff was implanted with and used one the Defendants' Implanted Catheter Products to facilitate regular long-term venous access for delivery of hydration, medication and/or nutritional supplementals, as well as the withdrawal of blood.

6. While contained within the Plaintiff's vasculature, one of the Defendants' Implanted Catheter Products malfunctioned and/or failed. Subsequently, the Plaintiff developed certain Injuries, Conditions, and Complications as a result of the malfunction(s) and/or failure(s) of one or more of the Defendants' Implanted Catheter Products.

7. The Plaintiff brings this action on her own behalf and on behalf of a class of persons in Canada who are similarly situated, to be further defined on the application for certification (the "Class" and/or "Class Members").

The Defendants

8. The Defendant Becton, Dickinson and Company, also known as BD ("BD"), is a global medical technology company with a principal place of business in Franklin Lakes, New Jersey, United States of America ("USA" or the "US"). In 2017, BD acquired the Defendant C.R. Bard, Inc., along with its subsidiaries and business units. As a result, Bard-branded products, including Implanted Catheter Products, are manufactured, marketed, distributed, and/or sold by BD entities. BD has responsibilities for Implanted Catheter Products in Canada.

9. The Defendant C.R. Bard, Inc. ("Bard") is a medical equipment company with a principal place of business in Franklin Lakes, New Jersey, USA. Bard is a wholly owned subsidiary of BD. Bard holds intellectual property rights for various Implanted Catheter Products. Bard has responsibilities for Implanted Catheter Products in Canada.

10. The Defendant Bard Access Systems, Inc. ("BAS") is a medical equipment company with a principal place of business in Salt Lake City, Utah, USA. BAS is a wholly owned subsidiary of BD. Prior to BD's 2017 acquisition of Bard, BAS was a wholly owned subsidiary of Bard. BAS is identified as the Health Canada licenced manufacturer of some or all Implanted Catheter Products in Canada and is listed on the product information documents for some or all Implanted Catheter Products. BAS has responsibilities for Implanted Catheter Products in Canada.

11. The Defendant Bard Peripheral Vascular, Inc. (“BPV”) is a medical equipment company with a principal place of business in Tempe, Arizona, USA. BPV is a wholly owned subsidiary of BD. Prior to BD’s 2017 acquisition of Bard, BPV was a wholly owned subsidiary of Bard. According to Defendants, BPV distributed Implanted Catheter Products. BPV has responsibilities for Implanted Catheter Products in Canada.

12. The Defendant Becton Dickinson Canada Inc. (“BD Canada”) is a medical equipment company with a principal place of business in Mississauga, Ontario. BD Canada is a wholly owned subsidiary of BD. BD Canada has responsibilities for Implanted Catheter Products in Canada.

13. The Defendant Bard Canada Inc. (“Bard Canada”) is a medical equipment company with a principal place of business in Mississauga, Ontario. Bard Canada is a wholly owned subsidiary of BD. Prior to BD’s 2017 acquisition of Bard, Bard Canada was a wholly owned subsidiary of Bard. Bard Canada has responsibilities for Implanted Catheter Products in Canada.

14. Hereinafter, each the above Defendants shall be collectively referred to as the “Defendants”.

15. 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, and/or subsidiary, Implanted Catheter Products in Canada.

16. At all material times, the Defendants were engaged in the business of designing, manufacturing, testing, packaging, promoting, marketing, distributing, labelling, and/or selling of Implanted Catheter Products in Canada. The development of Implanted Catheter 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 Implanted Catheter Products, and other actions central to the allegations of this lawsuit were undertaken by the Defendants in British Columbia and elsewhere.

Implantable Central Venous Catheters

17. Implanted Catheter Products are a form of implantable central venous catheters, which are vascular access devices used to provide “central line” or “central venous” access – i.e., access to a central vein (commonly the internal jugular, subclavian, or femoral) – and are designed to be implanted in the body and left in place long-term – in some cases for weeks, months, or years – to facilitate repeated direct access to the vascular system for the delivery of medication, intravenous fluids, parenteral nutrition solutions, blood products, and/or the withdrawal of blood samples. These devices are common in cancer patients who require repeat chemotherapy treatments, as well as in patients with severe autoimmune disorders.

18. All implantable central venous catheters comprise an implanted catheter component and some form of external access point.

19. The implanted catheter component is a small catheter that is implanted or tunnelled under the skin of an individual through a surgical opening, often in the

arm, neck, or chest, and threaded or placed into a large vein, typically at or near the heart. While the implanted catheter component remains in place in the patient, external catheters are then able to be connected to the patient to administer or draw fluids by way of an external access point to the implantable central venous catheter, which differs in design depending on the subtype of implantable central venous catheter that the patient has received.

20. In subcutaneous port catheters (also known by a variety of other names including venous access ports, intravenous ports, implanted ports, port catheters, port-a-caths, port-a-catheters, or simply “ports”), the implanted catheter stops at the surgical opening where the internal catheter was inserted and connects to a port (also known as a reservoir, chamber, or portal) that is placed completely under the skin at the surgical opening and which acts as the external access point. The port typically has a raised centre (or septum / injection reservoir) where needles are inserted to directly access the bloodstream through the internal catheter component placed inside a central vein.

21. In tunnelled central venous catheters (also known by other names including tunneled external catheters), the implanted catheter extends out of the surgical opening a small amount. The doctors will typically close the opening around the external portion of the implanted catheter and may stitch part of the catheter in place to the skin or use banding tape at the exit site to secure it to the body. The exit site is then covered and protected from infection using a sterile dressing. Outside of the body, the external portion of the catheter may be subdivided into one or more smaller tubes called lumens. Each lumen has a clamp, a needleless

connector (also called a hub), and a disinfection cap on the end, and acts as an access point to the implanted catheter.

The Defendants' Implanted Catheter Products

22. The Defendants' Implanted Catheter Products at issue in this litigation consist of implantable central venous catheters which were manufactured and distributed by the Defendants and licensed as medical devices for sale in Canada and which were constructed with a catheter component comprised of a polymeric mixture that includes barium sulfate and, in the case of a subset of Implanted Catheter Products, a port reservoir comprised of polyoxymethylene ("POM").

23. Multiple models of the Defendants' Implanted Catheter Products were marketed, distributed, and/or sold in Canada and/or to Canadians, including but not limited to the following:

    (a) BardPort implantable ports;

    (b) Groshong central venous catheters;

    (c) M.R.I. implantable ports;

    (d) PowerFlow implantable ports;

    (e) PowerHickman central venous catheters;

    (f) PowerPICC central venous catheters;

    (g) PowerPort implantable ports;

    (h) SlimPort implantable ports;

    (i) Titanium implantable ports;

(j) Vaccess CT implantable ports; and

(k) X-Port implantable ports.

24. The Defendants' products described in paragraphs 22-23 above are collectively referenced herein as "Implanted Catheter Products".

25. Health Canada approved Implanted Catheter Products for sale in Canada and Implanted Catheter Products are classified as Class III medical devices pursuant to the *Medical Devices Regulations*, SOR/98-282 of the *Food and Drugs Act*, RSC 1985, c F-27. Class III and IV medical devices pose the highest level of risk of all medical devices licenced for use in Canada.

26. The Defendants' Implanted Catheter Products have been and continue to be marketed to the medical community, and in turn to patients, as safe, effective, and reliable medical devices, which can be implanted by safe, effective, and minimally invasive surgical techniques. Implanted Catheter Products are marketed as being more and/or as safe and/or effective than alternatives.

27. The Defendants have distributed, marketed, and/or sold their Implanted Catheter Products to the medical community at large, and in turn to patients, through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include aggressive marketing to health care providers at medical conferences, hospitals, and private offices. The Defendants also utilize brochures and websites offering misleading expectations with respect to the safety and utility of their Implanted Catheter Products.

28. During the period of time that the Defendants' Implanted Catheter Products have been approved for use in Canada, there have existed safer and economically feasible alternatives that are at least as efficacious as the Defendants' Implanted Catheter Products and carry fewer and/or less serious risks than the Defendants' Implanted Catheter Products, including but not limited to conventional peripheral intravenous catheters, conventional peripherally inserted central catheters (PICCs), external or non-tunneled central venous catheters, tunneled central venous catheters and/or subcutaneously implanted ports which are manufactured with alternative materials and/or designs, including with alternative radiopaque materials (such as bismuth and tungsten) and without barium sulfate, as well as port-a-caths manufactured with plastic port reservoirs manufactured with stabilized POM, ultra-high molecular weight polyethylene, or a formulation of POM suitable for biomedical use and implantation within the body.

Common Defects of Implanted Catheter Products

29. The Defendants' Implanted Catheter Products suffer from common design and/or manufacturing defects.

30. These common defects include but are not limited to the use of barium sulfate in the catheter component of all Implanted Catheter Products; the absence of sheathing or coating surrounding the catheter in some or all Implanted Catheter Products; the absence of antimicrobial coatings, materials, and/or additives in some or all Implanted Catheter Products; the use of POM in the port reservoir of some Implanted Catheter Products; the presence of palpation bumps in some

Implanted Catheter Products; and a design for all Implanted Catheter Products that could not withstand repeated, long-term use as advertised.

Barium Sulfate Catheters

31. All Implanted Catheter Products contain a catheter component that is compromised of a polymeric mixture featuring barium sulfate.

32. Some Implanted Catheter Products have catheters comprised of a polymeric mixture of barium sulfate and polyurethane.

33. The polymeric mixture of polyurethane and barium sulfate that is used in the catheters in some Implanted Catheter Proucts is called “ChronoFlex.” Chronoflex is a biomaterial manufactured by AdvanSource Biomaterials Corporation, which is a division of Mitsubishi Chemical America, Inc.

34. Some Implanted Catheter Products, including the Defendants’ Groshong central venous catheters, have catheters comprised of a polymeric mixture of barium sulfate and silicone.

35. Some Implanted Catheter Products have catheters comprised of a polymeric mixture of barium sulfate with silicone and polyurethane.

36. Regardless of the model, the Defendants designed and manufactured all Implanted Catheter Products with catheter components containing barium sulfate.

37. Barium sulfate is a radiopaque substance, meaning it is visible during diagnostic imaging.

38. Barium sulfate is known to contribute to the reduction of the mechanical integrity of polyurethane while in the body, including if it is not encapsulated, coated, or separated from the catheter surface.

39. In addition, barium sulfate reduces the mechanical integrity of silicone *in vivo*.

40. When exposed to the bloodstream, barium sulfate particles will dissociate over time from the surface of the catheter component of an implantable central venous catheter.

41. When the particles of barium sulfate dissociate from the surface of a catheter over time, microfractures, fissures, and other alterations of the polymeric structure occur on the surface of the catheter, ultimately degrading the mechanical properties of the catheter.

42. Alterations and degradations of the polymeric structure of a catheter can cause injuries common to these devices including catheter fracture, catheter infection, and thromboembolism.

43. Cracks, fissures, divots, and pitting on the surface of the catheter can act as predetermined sites of fractures.

44. Cracks, fissures, divots, and pitting on the surface of the catheter can also harbor microbes, which can cause infection.

45. Cracks, fissures, divots, and/or pitting on the surface of the catheter can also cause thrombosis by permitting the collection and proliferation of fibrinous material present in the bloodstream. The collection of fibrinous material on the surface of a

biomaterial also potentiates infection by creating a hospitable environment for pathogens including bacteria and fungi.

46. The use of barium sulfate in the catheter component of the Defendants' Implanted Catheter Products is a common defect impacting all of the Defendants' Implanted Catheter Products.

47. The use of barium sulfate in the catheter component of the Defendants' Implanted Catheter Products significantly contributed to injuries suffered by the Plaintiff and/or Class Members.

Lack of Coating or Sheathing

48. Some or all of the Defendants' Implanted Catheter Products contain catheter components that lack a sufficient or any surface-modifying additive, functional coating, or antimicrobial coating.

49. The dissociation of barium sulfate particles *in vivo* from the surface of a catheter can be prevented, in whole or in part, by the inclusion of a surface-modifying additive coating.

50. The inclusion of a surface-modifying additive coating to the catheter component of an implantable central venous catheter can also result in a smoother surface, which can reduce susceptibility to bacterial adhesion, in whole or in part.

51. Where there is an absence of sufficient sheathing or coating on the catheter component of an implantable central venous catheter, barium sulfate more easily dissociates from the catheter's surface, resulting in alterations and degradations

of the polymeric structure of the catheter and leading to harms including catheter fracture, catheter infection, and thromboembolism.

52. The absence of sufficient sheathing or coating on the catheter component of some or all of the Defendants' Implanted Catheter Products is a common defect impacting some or all of the Defendants' Implanted Catheter Products.

53. The absence of sufficient sheathing or coating on the catheter component of some or all of the Defendants' Implanted Catheter Products significantly contributed to injuries suffered by the Plaintiff and/or Class Members.

Lack of Antimicrobial Additive

54. Some or all of the Defendants' Implanted Catheter Products were designed and manufactured without the use of sufficient or any antimicrobial materials, including but not limited to antimicrobial coatings and/or material modifications that involve the addition of antimicrobial additives.

55. Irregularities on the surface of a catheter, including cracks, fissures, divots, and pitting, can lead to enhanced bacterial colonization by creating a hospitable surface environment for microbes to collect and proliferate.

56. Microbes on the surface of the catheter can cause infection.

57. When implantable central venous catheters are designed and/or manufactured, the use of coatings, materials, and/or additives that contain antimicrobial properties, including the inclusion of bacteriostatic and bactericidal agents, can significantly reduce the prospect of infection.

58. The absence of any or sufficient antimicrobial coatings, materials, and/or additives in some or all of the Defendants' Implanted Catheter Products is a common defect impacting some or all of the Defendants' Implanted Catheter Products.

59. The absence of any or sufficient antimicrobial coatings, materials, and/or additives in some or all of the Defendants' Implanted Catheter Products significantly contributed to injuries suffered by the Plaintiff and/or Class Members.

Polyoxymethylene Ports

60. Some of the Defendants' Implanted Catheter Products were designed and manufactured utilizing polyoxymethylene in the construction of the port reservoir of their devices.

61. POM is a synthetic acetyl thermoplastic polymer, commonly marketed under the trade name Delrin.

62. The formulation of POM used within the design and manufacture of some of the Defendants' Implanted Catheter Products is Delrin 500 NC010.

63. Delrin 500 NC010 is provided by DuPont and is accompanied by a Medical Caution Statement indicating that the polymer should not be used for brief or temporary implantation within the body or contact with internal body fluids or tissues without DuPont's express acknowledgement of the contemplated use. Permanent implantation within the body is expressly forbidden.

64. Oxidative degradation of POM is known to occur during processing, within the body, and when exposed to radiography. Degradation of POM reduces the

mechanical properties of the polymer and releases toxins, in the form of formaldehyde, as a byproduct of degradation.

65. Degradation of the surface of the polymer within the port reservoir precipitates the formation of cracks, fissures, and other defects in the mechanical stability of the device. The formation of such surface defects contributes to an increased risk of biofilm formation, infection, and thrombosis.

66. The manufacturing process and design of the POM contained within the ports of some of the Defendants' Implanted Catheter Products lacks any or adequate measures to prevent oxidative degradation of the polymer.

67. The use of POM in the port reservoir component of some of the Defendants' Implanted Catheter Products is a common defect impacting some of the Defendants' Implanted Catheter Products.

68. The use of POM in the port reservoir component of some of the Defendants' Implanted Catheter Products significantly contributed to injuries suffered by the Plaintiff and/or Class Members.

Palpation Bumps

69. Some of the Defendants' Implanted Catheter Products were designed and manufactured with palpation bumps in the construction of their devices.

70. Some of the Defendants' Implanted Catheter Products are power-injectable.

71. Power-injectable ports allow for contrast material to be injected at a higher rate than by hand injection, facilitating medical imaging.

72. Some of the Defendants' Implanted Catheter Products are denominated with prefix "Power" to signify the device as power injectable, including the Defendants' "PowerPort," "PowerFlow," and "Power-Injectable" devices.

73. Some of the Defendants' Implanted Catheter Products have an external access point with three raised "palpation bumps" in a triangular configuration to distinguish them as power injectable.

74. After implantation, the palpation bumps cause undue compression stress on the tissue of the subcutaneous pocket into which the port is placed.

75. Such compression stress leads to ulceration and tissue necrosis, which potentiates port infections and catheter infections and causes erosion of the port through the patient's skin.

76. The incidence of tissue erosion associated with the Defendants' Implanted Catheter Products is unreasonably high. Some medical institutions have implemented policies prohibiting the placement of ports with palpation bumps due to the high rate of erosion.

77. The use of palpation bumps in some of the Defendants' Implanted Catheter Products is a common defect impacting some of the Defendants' Implanted Catheter Products.

78. The use of palpation bumps in some of the Defendants' Implanted Catheter Products significantly contributed to injuries suffered by the Plaintiff and/or Class Members.

The Risks of Implanted Catheter Products

79. Contrary to the representations made to the medical community, and ultimately to the patients themselves, the Defendants' Implanted Catheter Products have high failure, injury, and complication rates, fail to perform as intended, require frequent and often debilitating additional surgery, and cause severe and irreversible Injuries, Conditions, and Complications to a significant number of individuals, including the Plaintiff and other putative Class Members.

80. The Injuries, Conditions, and Complications suffered due to the Defendants' Implanted Catheter Products include but are not limited to catheter fractures, perforations, migration, and other degradations and alterations (including microfractures, fissures, and other alterations of the polymeric structure), hemorrhage, cardiac/pericardial tamponade, cardiac arrhythmia and other symptoms similar to myocardial infarction, severe and persistent pain, perforations of tissue, vessels and organs, blood clots, thrombosis (including deep vein thrombosis), embolisms (including pulmonary embolisms, thromboembolisms, etc.), infections, bacterial colonization, stroke, sepsis, necrosis, as well as failure, delay, and complications with medical treatments (including clogging or leaking in catheters, extravasation of chemotherapy medications, and failures of intravenous fluids from being delivered as intended), and death (collectively, the "Injuries, Conditions, and Complications").

81. The failures of the Defendants' Implanted Catheter Products are caused or contributed to by their shared common design defects, including, but not limited to, the use of barium sulfate in their design.

82. The Defendants' Implanted Catheter 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 physicians.

83. The Defendants' Implanted Catheter Products have high failure, injury, and complication rates, fail to perform as intended, have resulted in serious and irreversible injuries, conditions, and have caused damage to the Plaintiff and other putative Class Members.

84. The Defendants' Implanted Catheter Products create risks to the health and safety of the patients that are far more significant than the risks posed by other products available to treat the underlying medical conditions and which far outweigh the utility of their Implanted Catheter Products.

The Defendants Knew or Ought to Have Known of the Risks

85. The Defendants knew or ought to have know that their Implanted Catheter Products are defective and are not properly manufactured to withstand normal, foreseeable, and intended use.

86. Shortly after the Defendants introduced these devices into the market — and long before the Plaintiff was implanted with an Implanted Catheter Product — the Defendants received notice of numerous adverse event reports concerning Implanted Catheter Products.

87. Health Canada's database of Medical Device Incidents includes a sizeable number of reports involving Implanted Catheter Products. Reports received in the database through June 2023 include over 2,280 incidents that involve the terms "Bard" and

"catheter," over 380 incidents that involve the terms "Bard" and "implant," and over 200 incidents that that involve the terms "Bard," "catheter," and "implant".

88. In addition to the volume of adverse event reports, the Defendants' catheter products were also the subject of many product recalls in the US and Canada, including:

(a) a Health Canada recall initiated by BAS in January 2023 for multiple types of Hickman And Leonard Lumen CV Catheters products, including:

(i) the External Catheter Segment For Hickman 12.5 F Triple-Lumen CV Catheters,

(ii) the Red Adapter Leg For Hickman And Leonard Multiple Lumen CV Catheters, and

(iii) the White Adapter Leg For Hickman And Leonard Multiple Lumen CV Catheters;

(b) a Health Canada recall initiated by BAS in April 2021 for multiple types of Groshong Catheter Products, including:

(i) the Groshong NXT, 4Fr Connector Repair Kit,

(ii) the Groshong, Basic Tray With Sherlock Stylet, Without Microintroducer,

(iii) the Groshong, Basic Tray With Sherlock Stylet And Microintroducer, Single Lumen,

(iv) the Groshong NXT ClearVUE Catheter With Sherlock 3CG Tip Positioning System (TPS) Stylet, Basic Kit, Single Lumen,

(v) the Groshong NXT ClearVUE Catheter With Sherlock 3CG Tip Positioning System (TPS) Stylet, Full Kit, and

(vi) Groshong Peripherally Inserted Central Catheter Trays;

(c) an FDA recall initiated in March 2021 by BPV for PowerPort duo M.R.I. Implantable Port, with attachable 9.5F Polurethane Open-Ended Dual-Lumen Venous Catheter products;

(d) a Health Canada recall initiated in February 2020 by BAS for BardPort Slim Titanium Low Profile Implanted Port with Attachable Open End products;

(e) an FDA recall initiated in January 2020 by BPV for BARD Access Systems PowerPort ClearVUE Slim Implantable Port With Smooth Septum and Attachable 6 F Polyurethane Open-Ended Single-Lumen Venous Catheter products;

(f) an FDA recall initiated in October 2019 by BPV for multiple types of catheter products, including:

(i) the BardPort M.R.I. Hard Base Implantable Port with Attachable 9.6 F Open-Ended Single-Lumen Venous Catheter,

(ii) the BardPort M.R.I. Implantable Port with Attachale 9.6 F Open-Ended Single-Lumen Venous Catheter,

(iii) the BardPort Titanium Implantable Port with Attachable 9.6 F Open-Ended Single-Lumen Venous Catheter,

(iv) the PowerFlow Implatable Apheresis IV Port with attachable 9.6 F ChronoFl x Open-Ended Single-Lumen Venous Catheter,

(v) the PowerPort Implantable Port With Attachable 9.6 F Open-Ended Single-Lumen Venous Catheter,

(vi) the PowerPort Implantable Port with Pre-Attached 9.6 F Open-Ended Single-Lumen Venous Catheter,

(vii) the PowerPort isp M.R.I. Implantable Port with Attachable 9.6 F Open-Ended Single-Lumen Venous Catheter with Suture Plugs,

(viii) the PowerPort isp M.R.I. Implantable Port With Attachable 9.6 F Open-Ended Single-Lumen Venous Catheter Without Suture Plugs,

(ix) the PowerPort isp M.R.I. Implantable Port with Pre-Attached 9.6 F Open-Ended Single-Lumen Venous Catheter without Suture Plugs,

(x) the PowerPort isp M.R.I. Implantable Port with Pre-Attached 9.6 F Open-Ended Single-Lumen Venous Catheter with Suture Plugs,

(xi) the PowerPort M.R.I. Implantable Port with Attachable 9.6 F Open-Ended Single-Lumen Venous Catheter with Suture Plugs,

(xii) the PowerPort M.R.I. Implantable Port with Attachable 9.6 F Open-Ended Single-Lumen Venous Catheter Without Suture Plugs,

(xiii) the PowerPort M.R.I. Implantable Port With Pre-Attached 9.6 F Open-Ended Single-Lumen Venous Catheter with Suture Plugs,

(xiv) the Vaccess CT Power-Injectable Implantable Port with Suture Plugs,

(xv) the X-Port isp M.R.I Implantable Port, with Pre-Attached 9.6 F Open-Ended Single-Lumen Venous Catheter, and

(xvi) the X-Port isp M.R.I. Implantable Port, with Attachable 9.6 F Open-Ended Single-Lumen Venous Catheter;

(g) a Health Canada recall initiated in September 2019 by BAS of multiple types of M.R.I. Implantable Port products, including:

(i) the BardPort M.R.I. Hard Base Implantable Port,

(ii) the X-Port isp M.R.I. Implantable Port, and

(iii) the PowerPort isp M.R.I. Implantable Port;

(h) an FDA recall initiated in February 2019 by BPV for PowerPort isp M.R.I. Implantable Port with Attachable 8F Polyurethane Open-Ended Single-Lumen Venous Catheter products;

(i) an FDA recall initiated in June 2018 by BPV for multiple types of Powerport Cleavue Slim Implantable Port products, including:

(i) PowerPort ClearVUE isp, 6F ChronoFlex Catheter, Intermediate Nautilus Delta Kit,

(ii) PowerPort ClearVUE isp, 8F ChronoFlex Catheter, Intermediate Nautilus Delta Kit,

(iii) PowerPort ClearVUE Slim, 6F ChronoFlex Catheter and Suture Plugs, Intermediate Nautilus Delta Kit,

(iv) PowerPort ClearVUE Slim, 8F ChronoFlex Catheter and Suture Plugs, Intermediate Nautilus Delta Kit, and

(v) Nautilus Delta Tip Confirmation System (Includes: Netbook with Pre-loaded Software, Patient Module, and ECG Cable);

(j) an FDA recall initiated in February 2018 by BPV for multiple types of PowerPort ClearVUE products, including:

(i) the PowerPort ClearVUE isp Implantable Port With Smooth Septum and Attachable 8F Polyurethane Open-Ended Single-Lumen Venous Catheter Custom Kit,

(ii) the PowerPort ClearVUE isp with Smooth Septum, 6F ChronoFlex, Polyurethane Catheter,

(iii) the PowerPort ClearVUE isp with Smooth Septum, 8F ChronoFlex, Polyurethane Catheter,

(iv) the PowerPort ClearVUE Slim Implantable Port with Smooth Septum and Attachable 8F Polyurethane Open-Ended Single-Lumen Venous Catheter Custom Kit,

(v) the PowerPort ClearVUE Slim with Smooth Septum, 6F ChronoFlex Silk, Polyurethane Catheter,

(vi) the PowerPort ClearVUE Slim with Smooth Septum, 6F ChronoFlex Silk, Polyurethane Catheter with Open Suture Holes,

(vii) the PowerPort ClearVUE Slim with Smooth Septum, 6F ChronoFlex, Polyurethane Catheter with Open Suture Holes,

(viii) the PowerPort ClearVUE Slim with Smooth Septum, 8F ChronoFlex, Polyurethane Catheter,

(ix) the PowerPort ClearVUE Slim with Smooth Septum, 8F ChronoFlex, Polyurethane Catheter with Open Suture Holes, and

(x) the PowerPort(R) ClearVUE(R) isp with Smooth Septum, 6F ChronoFlex(TM), Polyurethane Catheter;

(k) an FDA recall initiated in February 2014 by BAS for PowerPort Slim Implantable Port products;

(l) an FDA recall initiated in December 2013 by BAS for multiple types of catheter products, including:

(i) the MRI Low Profile Single Lumen port with Open-Ended 6.6Fr Silicone Catheter, and

(ii) the Titanium Single Lumen Low-Profile port, with Pre-Attached open-Ended Silicone 6.6Fr Catheter;

(m) an FDA recall initiated in May 2013 by BPV for Bard Peripheral Vascular Vaccess PTA Balloon Dilatation Catheters, 8mm x 4cm x 80cm;

(n) an FDA recall initiated in February 2012 by BAS for BardPort M.R.I. Implanted Port with Attachable 6 Fr. ChronoFlex Open-Ended Single-Lumen Venous Catheter and Peel-Apart Introducer Kit products;

(o) an FDA recall initiated in August 2011 by BAS for BardPort Titanium Implanted Port products; and

(p) an FDA recall initiated in March 2010 by BAS for PowerPort isp M.R.I Implanted Port without Suture Plugs with attachable 6F Chronoflex Polyurethane Open-ended Single -Lumen Venous Catheter products.

89. The Defendants also knew or ought to have know of numerous scientific articles and studies that identified the potential risks of implantable vascular access devices to cause serious injuries. For example:

(a) a 2020 study, which examined a participant pool of over 93,000 patients who had been implanted with a port-a-catheter, found that complications of any kind within 5 years were very common (over 59%), including arrhythmogenic complications (over 32%), thrombovascular complications (over 36%), infection complications (over 17%), and mechanical complications (over 10%);

(b) a meta-analysis from 2020, which reviewed 80 studies and a participant pool of over 39,000 patients, examined the association between totally implantable venous access ports (TIVAPs) and venous thromboembolism (VTE) as compared to external central venous catheters in cancer patients and found that TIVAPs inserted in the upper-extremity vein had a VTE risk of over 3.5%, which denoted a statistically significant difference;

(c) a 2019 study, which involved 66 patients who underwent totally implantable venous access device implantation with Bard catheters, opined that late catheter fracture is a well-known complication of totally implantable venous access devices and concluded it is a particular risk in certain Bard catheters;

(d) a 2018 scientific article showed that continuous contact of the catheter with tissues and patient fluids resulting in the formation of a biofilm on the catheter, which is a perfect environment for the development of infection;

(e) a study from 2017, which tracked over 130 patients who had been implanted with Bard PowerPorts over a brief period of less than 20 months, identified postoperative complications in over 6% of patients, including multiple incidences of infections and extravasation;

(f) a 2016 scientific publication showed that the loss of barium sulphate filler particles near the surface of a catheter results in preformed microscopic notches, which act as predetermined sites of fracture and complete mechanical failure;

(g) a 2016 scientific article in which the authors found that the roughness and thrombogenicity of various catheters was associated with the presence of radiopaque particles embedded in the catheters and that the choice of the material in a catheter, and subsequent degradation when exposed to the bloodstream, has significant impact on catheter durability and catheter-related complications;

(h) a 2015 study, which examined the risk of blood stream infections among 552 patients who had been implanted with one of two types of venous ports including BardPorts, identified 34 episodes of blood stream infections among the participants within a three-year period;

(i) a study from 2013, which looked at nearly 300 patients who had undergone venous port catheter implantations with either a Bard port or an alternative product from a different manufacturer, found that all the patients among the cohort who experienced venous port migration had been implanted with Bard ports and that Bard ports had a migration rate of 6.7%;

(j) a study from 2011, which examined a participant pool of over 1,500 patients including over 1,000 patients with Bard catheters, found that material weakness was the main cause of catheter fractures and that the majority of patients with fractured catheters were asymptomatic until regular plain chest films were obtained;

(k) a 2010 peer-reviewed scientific publication showed that when barium sulfate impregnated catheters are exposed to the bloodstream barium sulfate particles release, resulting in surface irregularities predisposing to bacterial proliferation and that barium sulfate release can be prevented by surface-modifying additive coating and that obtaining a smoother surface by surface-modifying additive coating reduces susceptibility to bacterial adhesion;

(l) a study from 2010, which reviewed the mechanisms of failure of implantable ports in 73 unique cases of catheter fracture (nearly half of whom were implanted with Bard products), concluded that the cause of easily fracture may be associated with the design of totally implantable access ports;

(m) a 2007 article showed that when barium sulfate degrades *in vivo* it causes cracks, fissures, divots, and/or pitting on the surface of the catheter; and

(n) a study from 2006, which examined a participant pool of over 300 patients who underwent insertion and/or removal surgeries of implantable vascular access devices almost exclusively manufactured by Bard Access Systems, concluded that mechanical port complications were not rare for these devices, with over 5% suffering from complications, and that there was a risk of perforation not seen in other devices.

90. At all material times, the Defendants knew or should have known that the risks of using their Implanted Catheter Products included severe Injuries, Conditions, and Complications.

91. Despite the Defendants' actual or imputed knowledge of the Injuries, Conditions, and Complications caused by their Implanted Catheter Products, the Defendants have, and continue to, manufacture, market, and sell their Implanted Catheter Products, without adequately warning, labeling, instructing, and/or disseminating information with respect to these risks, either prior to and/or after the marketing and sale of the Implanted Catheter Products.

92. The instructions for use and other written disclosures accompanying the Implanted Catheter Products, which were provided to patients, physicians, and/or Health Canada, failed to list negative effects and possible complications, including, but not limited to, the risk of Injuries, Conditions, and Complications.

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

94. At all material times, the Defendants, through their servants and agents, failed to adequately warn physicians and consumers, including the Plaintiff and other putative Class Members, of the risk of Injuries, Conditions, and Complications caused by their Implanted Catheter Products.

The Plaintiff's Experience

95. The Plaintiff, Shirley Antonelli, is an individual residing in Coal Harbour, BC who has been diagnosed with diabetes insipidus, a condition that causes fluids in the body to become out of balance, which can cause severe dehydration, and that is characterized by symptoms of extreme thirst and frequent urination.

96. In or around November 2021, the Plaintiff underwent a surgical procedure to have one of the Defendants' Implanted Catheter Products – a Bard PowerPICC SOLO catheter – inserted within her body to facilitate regular long-term venous access, including in particular to provide the delivery of hydration and other supplements due to dehydration experienced as a result of then-undiagnosed diabetes insipidus.

97. From 2021 to 2023, the Plaintiff was implanted with and used the Defendants' Implanted Catheter Product for delivery of hydration, iron infusion, and other medication and supplements, as well as the withdrawal of blood.

98. While implanted with an Implanted Catheter Product, the Plaintiff suffered Injuries, Conditions, and Complications caused by the Implanted Catheter Product.

99. While implanted with an Implanted Catheter Product, the Product suffered malfunction and/or failure. While implanted in the Plaintiff's body, components of the device separated from each other and migrated within the Plaintiff's body.

100. Subsequent to receiving an Implanted Catheter Product, the Plaintiff developed infection, blood clotting, and/or vascular damage requiring additional medical treatments.

101. In 2023, the Plaintiff began to experience frequent, recurring, and severe negative physical symptoms, including reoccurring instances of shortness of breath and heart palpitations, as well as significant bodily pain. Due to the frequency and severity of her physical symptoms, the Plaintiff needed to work from home and required recurring supplemental concentrations of oxygen.

102. The Plaintiff's physical symptoms worsened over time and in August 2023 the Plaintiff required an ambulance to take her to the Port McNeill Hospital in Port McNeill, BC, which was the closest hospital to her then residence.

103. At the Port McNeill Hospital, the Plaintiff was put on an IV, provided with antibiotics, and monitored by medical professionals. In or around one or two days after her admission to the Port McNeill Hospital, the Plaintiff was advised by her treating medical professionals that it was medically necessary for her to be transported to a larger hospital for more specialized care and treatment.

104. The Plaintiff was subsequently sent by ambulance to the North Island Hospital in Campbell River, BC, which is over 2 hours drive from Port McNeill.

105. During the ambulance ride to Campbell River, the Plaintiff's health worsened, and she was advised by the transporting medical professionals that the situation had become an emergency. She was rushed to the North Island Hospital's Emergency Department and was admitted to the Intensive Care Unit within a short time after arrival at the hospital.

106. The Plaintiff's treating medical professionals at the North Island Hospital advised her that as a result of her physical condition it was medically necessary to remove the Implanted Catheter Product as soon as possible.

107. As a result of the Injuries, Conditions, and Complications caused by the Implanted Catheter Product, the Plaintiff underwent a surgical procedure to remove the Implanted Catheter Product while at the North Island Hospital in or around August 2023.

108. The Plaintiff was kept at the North Island Hospital for multiple days after her removal procedure in order for medical professionals to monitor her physical condition. The Plaintiff ultimately was forced to stay at the North Island Hospital for approximately 5 days.

109. The Plaintiff was ultimately diagnosed with a rare severe form of infection and blood clotting, all of which had developed while she was implanted with the Defendants' Implanted Catheter Product.

110. Following the post-operative period after the removal of the Defendants' Implanted Catheter Product, the Plaintiff continued to experience medical problems, including with dehydration, pain, and difficulties in securing intravenous access to her veins

to receive vital medication, fluids, and other nutritional supplements. The Plaintiff required subsequent follow-ups with medical professionals in order to monitor her post-operative recovery and ongoing medical issues.

111. As a result of the Defendants' defective Implanted Catheter Product, the Plaintiff suffered serious, prolonged and/or permanent physical injuries, including damage to her vasculature and tissues within her body.

112. Prior to and at the time when Plaintiff underwent a surgical procedure where she was implanted with one of the Defendants' Implanted Catheter Products, she received no or inadequate warning about the risk of developing Injuries, Conditions, and Complications.

113. Had the Plaintiff been aware of the magnitude of risks of developing Injuries, Conditions, and Complications, she would never have agreed to being implanted with the Defendants' Implanted Catheter Product. But for the Defendants' wrongful conduct, the Plaintiff would not have incurred damages.

114. The Plaintiff, Shirley Antonelli, and other Class Members have suffered and continue to suffer damages including financial expenses and special damages due to the wrongful conduct of the Defendants.

PART 2: RELIEF SOUGHT

115. The Plaintiff claims, on her own behalf and on behalf of all members of the proposed Class, as follows:

(a) an order certifying this action as a class proceeding and appointing her as representative Plaintiff for the Class, to be further defined on the application 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 Implanted Catheter Products;

(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 who was implanted with any of the Defendants' Implanted Catheter 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 any of the Defendants' Implanted Catheter 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 sale of their Implanted Catheter Products;

(g) damages for family members, pursuant to provincial and/or territorial legislation and the common law in each province and/or territory, where applicable, including the *Family Compensation Act,* RSBC 1996, c 126;

(h) punitive, aggravated, and exemplary damages in an amount to be determined at trial;

(i) costs for the administration of any court award or judgment obtained in this action;

(j) recovery of health care costs incurred by the Ministry of Health on their behalf pursuant to the *Health Care Costs Recovery Act*, SBC 2008, c 27 and similar legislation in other provinces and/or territories, where applicable;

(k) interest pursuant to the *Court Order Interest Act*, RSBC 1996, c 79; and

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

PART 3: LEGAL BASIS

116. In bringing this action on behalf of all residents of Canada who were implanted with an Implanted Catheter Product at any time on or before the date of the certification order, the Plaintiff pleads and relies upon the provisions of the *Class Proceedings Act*, RSBC 1996, c 50, as amended and regulations thereunder, the *Food and Drugs Act*, RSC 1985, c F-27 as amended and regulations thereunder, the *Negligence Act*, RSBC 1996 c 333, as amended and regulations thereunder, the *Court Rules Act*, RSBC 1996, c 80, as amended and regulations thereunder, and the *Court Jurisdiction and Proceedings Transfer Act*, SBC 2003, c 28, as amended and regulations thereunder. The Plaintiff also brings 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 pleads and relies upon the applicable provincial and/or territorial legislation and common law,

including the *Family Compensation Act,* RSBC 1996, c 126 as amended and regulations thereunder.

Causes of Action

Negligence

117. The Defendants at all material times owed a duty of care to the Plaintiff to:

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

(b) design their Implanted Catheter Products so as to avoid safety risks and to make them reasonably safe for their intended purposes;

(c) see that there were no defects in manufacture of their Implanted Catheter Products that were likely to give rise to injury in the ordinary course of use;

(d) conduct appropriate testing to determine whether and to what extent use of their Implanted Catheter Products posed serious health risks, including the magnitude of risk of developing Injuries, Conditions, and Complications;

(e) ensure that physicians were kept fully and completely warned and informed regarding all risks associated with their Implanted Catheter Products, including the increased risk of developing Injuries, Conditions, and Complications with use of Implanted Catheter Products compared to alternatives, including but not limited to conventional peripheral intravenous catheters, conventional peripherally inserted central catheters (PICCs), external or non-tunneled central venous catheters, as well as tunneled central venous catheters (with or without a subcutaneous cuff) and/or

subcutaneously implanted ports which are manufactured with alternative materials and/or designs, including with alternative radiopaque materials (such as bismuth and tungsten) and without barium sulfate;

(f) properly, adequately, and fairly warn consumers, including the Plaintiff and other putative Class Members, of dangers inherent in the use of their Implanted Catheter Products of which the Defendants' knew or ought to have known, including the increased risk of developing Injuries, Conditions, and Complications with use of Implanted Catheter Products compared to alternatives, including but not limited to conventional peripheral intravenous catheters, conventional peripherally inserted central catheters (PICCs), external or non-tunneled central venous catheters, as well as tunneled central venous catheters (with or without a subcutaneous cuff) and/or subcutaneously implanted ports which are manufactured with alternative materials and/or designs, including with alternative radiopaque materials (such as bismuth and tungsten) and without barium sulfate;

(g) monitor, investigate, evaluate and follow up on adverse reactions to the use of their Implanted Catheter Products; and

(h) properly inform Health Canada and other regulatory agencies of all risks associated with their Implanted Catheter Products.

118. The Defendants negligently breached their duty of care.

119. The Plaintiff states that her damages and the damages of other putative Class Members were caused by the negligence of the Defendants. Such negligence includes, but is not limited to the Defendants:

(a) failure to ensure that their Implanted Catheter 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) failure to ensure that their Implanted Catheter Products were free of any manufacturing defects that would expose recipients to Injuries, Conditions, and Complications;

(c) failure to adequately test their Implanted Catheter 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;

(d) designing their Implanted Catheter Products in a way which created a substantial likelihood of harm when there existed safer alternative designs and/or products which were economically feasible to manufacture;

(e) failure to provide Health Canada complete and accurate information with respect to their Implanted Catheter Products as it became available;

(f) failure to conduct any or any adequate follow-up studies on the efficacy and safety of their Implanted Catheter Products;

(g) failure to conduct any or any adequate long-term studies of the risks of their Implanted Catheter Products;

(h) failure to provide the Plaintiff, her physicians and Health Canada with proper, adequate, and/or fair warning of the risks associated with use of their Implanted Catheter Products, including but not limited to risk of Injuries, Conditions, and Complications;

(i) failure to adequately monitor, evaluate and act upon reports of adverse reactions to their Implanted Catheter Products in Canada and elsewhere;

(j) failure to provide any or any adequate updated and/or current information to the Plaintiff, physicians and/or Health Canada respecting the risks of their Implanted Catheter Products as such information became available from time to time;

(k) failure to provide adequate warnings of the risks associated with their Implanted Catheter Products, including the risk of Injuries, Conditions, and Complications in all persons receiving their Implanted Catheter Products on the patient information pamphlets in Canada;

(l) failure, after noticing problems with their Implanted Catheter Products, to issue adequate warnings, timely recall their Implanted Catheter Products, publicize the problems and otherwise act properly and in a timely manner to alert the public, including adequately warning the Plaintiff and her physician of their Implanted Catheter Products' inherent dangers, including but not limited to the danger of Injuries, Conditions, and Complications;

(m) failure to establish any adequate procedures to educate their sales representatives and physicians respecting the risks associated with their Implanted Catheter Products;

(n) representation that their Implanted Catheter 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) misrepresentation of the state of research pertaining to the purported benefits of their Implanted Catheter Products and their associated risks, including the risk of Injuries, Conditions, and Complications;

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

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

(r) failure to conform with applicable disclosure and reporting requirements pursuant to the *Food and Drugs Act*, RSC 1985, c F-27 and its associated regulations;

(s) failure to properly supervise their employees, subsidiaries and affiliated corporations;

(t) breach of other duties of care to the Plaintiff and other 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 Plaintiff and other putative Class Members.

120. The Defendants' Implanted Catheter Products were defective because they are unreasonably dangerous, beyond the dangers which could reasonably have been contemplated by the Plaintiff, putative Class Members, and/or their physicians. Any benefit from using the Defendants' Implanted Catheter Products is outweighed by the serious and undisclosed risks associated with their use, when used as the Defendants intended. There are no individuals for whom the benefits of the Defendants' Implanted Catheter Products outweigh the risks, given that there are many alternatives that are at least as efficacious as the Defendants' Implanted Catheter Products and carry fewer and/or less serious risks than the Defendants' Implanted Catheter Products, including but not limited to conventional peripheral intravenous catheters, conventional peripherally inserted central catheters (PICCs), external or non-tunneled central venous catheters, as well as tunneled central venous catheters (with or without a subcutaneous cuff) and/or subcutaneously implanted ports which are manufactured with alternative materials and/or designs, including with alternative radiopaque materials (such as bismuth and tungsten) and without barium sulfate.

121. The risks associated with use of the Defendants' Implanted Catheter Products, including Injuries, Conditions, and Complications in all persons receiving their Implanted Catheter Products, were in the exclusive knowledge and control of the Defendants. The extent of the risks was not known to, and could not have been

known by, the Plaintiff and other putative Class Members. The injuries of the Plaintiff and other putative Class Members would not have occurred but for the negligence of the Defendants in failing to ensure that their Implanted Catheter Products were safe for use or, in the alternative, for failing to provide an adequate warning of the risks associated with using their Implanted Catheter Products to the Plaintiff and other putative Class Members and to their physicians.

Damages

122. The Plaintiff and other putative Class Members' injuries and damages were caused by the negligence of the Defendants, their servants, and/or their agents.

123. As a result of the Defendants' negligence, the Plaintiff and other putative Class Members have suffered and continue to experience serious personal injuries and harm with resultant pain and suffering.

124. As a result of the conduct of the Defendants, the Plaintiff 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.

125. 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' Implanted Catheter Products.

126. Some of the expenses related to the medical treatment that the Plaintiff and other putative Class Members have undergone, and will continue to undergo, have been borne by the various provincial and/or territorial health insurers. As a result of the

negligence of the Defendants, the various provincial and/or territorial health insurers have suffered and will continue to suffer damages for which they are entitled to be compensated by virtue of their right of subrogation in respect of all past and future insured services. These subrogated interests are asserted by the Plaintiff and the putative Class Members pleading and relying upon the *Health Care Costs Recovery Act*, SBC 2008, c 27 and similar legislation in other provinces and/or territories, where applicable.

127. The Plaintiff claims punitive, aggravated, and exemplary damages for the reckless and unlawful conduct of the Defendants.

128. The Defendants engaged in conduct that is appropriately characterized as a marked departure from ordinary standards of decent behaviour. The Defendants egregiously overlooked and/or deceitfully withheld information regarding serious risks with Implanted Catheter Products. The Defendants failed to provide any warning or any adequate warning of the risks of Injuries, Conditions, and Complications, despite a preponderance of scientific literature and other reports that linked Implanted Catheter Products to these risks.

Jurisdiction

129. There is a real and substantial connection between British Columbia and the facts alleged in this proceeding. The Plaintiff and other putative Class Members plead and rely upon the *Court Jurisdiction and Proceedings Transfer Act*, SBC 2003, c 28 in respect of the Defendants. Without limiting the foregoing, a real and substantial connection exists between British Columbia and the facts alleged in

this proceeding pursuant to sections 10 (f) to 10 (h) of the *Court Jurisdiction and Proceedings Transfer Act*, SBC 2003, c 28 because this proceeding:

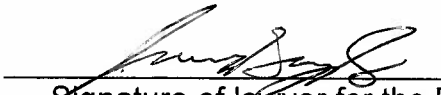
(a) concerns restitutionary obligations that, to a substantial extent, arose in British Columbia;

(b) concerns a tort committed in British Columbia; and

(c) concerns a business carried on in British Columbia.

Plaintiff's address for service:	**Siskinds LLP** **Barristers & Solicitors** 555 Burrard Street, Suite 16-111 Vancouver, BC, V7X 1M8
Fax number address for service (if any):	1.519.660.7859
E-mail address for service (if any):	jill.mccartney@siskinds.com
Place of trial:	Vancouver, British Columbia
The address of the registry is:	800 Smithe Street, Vancouver, BC, V6Z 2E1

Date: 22 APR 2024



Signature of lawyer for the Plaintiff
Jill S. McCartney
James E. Boyd
Charles M. Wright

Rule 7-1 (1) of the Supreme Court Civil Rules states:

> (1) Unless all parties of record consent or the court otherwise orders, each party of record to an action must, within 35 days after the end of the pleading period,
>
> > (a) prepare a list of documents in Form 22 that lists
> >
> > > (i) all documents that are or have been in the party's possession or control and that could, if available, be used by any party at trial to prove or disprove a material fact, and
> >
> > > (ii) all other documents to which the party intends to refer at trial, and
> >
> > (b) serve the list on all parties of record.

Appendix

Part 1: CONCISE SUMMARY OF NATURE OF CLAIM:

This is a claim for injuries, loss and damages suffered as a result of the Defendants' negligence in the design, development, testing, research, manufacture, licensing, labelling, warning, marketing, distribution, and sale of their Implanted Catheter Products.

Part 2: THIS CLAIM ARISES FROM THE FOLLOWING:

A personal injury arising out of:

[ ] a motor vehicle accident
[ ] medical malpractice
[x] another cause

A dispute concerning:

[ ] contaminated sites
[ ] construction defects
[ ] real property (real estate)
[ ] personal property
[x] the provision of goods or services or other general commercial matters
[ ] investment losses
[ ] the lending of money
[ ] an employment relationship
[ ] a will or other issues concerning the probate of an estate
[ ] a matter not listed here

Part 3: THIS CLAIM INVOLVES:

[x] a class action
[ ] maritime law
[ ] aboriginal law
[ ] constitutional law
[ ] conflict of laws
[ ] none of the above
[ ] do not know

Part 4:

Class Proceedings Act, RSBC 1996, c 50
Food and Drugs Act, RSC, 1985, c F-27
Negligence Act, RSBC 196 c 333
Family Compensation Act, RSBC 1996, c 126
Health Care Costs Recovery Act, SBC, 2008, c 27
Court Jurisdiction and Proceedings Transfer Act, SBC 2003, c 28

ENDORSEMENT ON ORIGINATING PLEADING OR PETITION FOR SERVICE OUTSIDE BRITISH COLUMBIA

The Plaintiff, Shirley Antonelli, claims the right to serve this pleading on the Defendants outside British Columbia on the ground that there is a real and substantial connection between British Columbia and the facts alleged in this proceeding and the Plaintiff and other Class Members plead and rely upon the *CJPTA* in respect of these Defendants. Without limiting the foregoing, a real and substantial connection between British Columbia and the facts alleged in this proceeding exists pursuant to section 10(f) to 10(h) of the *CJPTA* because this proceeding:

(f) concerns restitutionary obligations that, to a substantial extent, arose in British Columbia;

(g) concerns a tort committed in British Columbia; and

(h) concerns a business carried on in British Columbia.