C A N A D A PROVINCE OF QUEBEC DISTRICT OF MONTRÉAL

NO: 500-06-000784-161

SUPERIOR COURT

(Class Action)

PATRICK THOMAS WALLACE residing at 1485, Poirier Street, appartment 3, Montréal, Québec, H4L 1H5, Canada

Applicant;

٧.

COOK MEDICAL INCORPORATED, doing business under COOK MEDICAL INC., legal person, having a place of business at 400 Daniels Way, Bloomington, Indiana, 47404, United States

And

COOK INCORPORATED, legal person, having a place of business at 750 Daniels Way, Bloomington, Indiana, 47404, United States

And

COOK (CANADA) INC., legal person, having a place of business at 165 Mostar Street, Stouffville, Ontario, L4A 0Y2, Canada

And

COOK GROUP INC., legal person, having a place of business at 750 Daniels Way, P.O. Box 1608 Bloomington, Indiana, 47402, United States

And

WILLIAM COOK EUROPE APS, legal person, having a place of business at Sandet 6, 4632 Bjaeversok, Danemark

Defendants.

APPLICATION FOR AUTHORIZATION TO INSTITUTE A CLASS ACTION AND TO APPOINT THE STATUS OF REPRESENTATIVE PLAINTIFF

(ND: 67-182 IVC Filters)
(Article 575 C.C.P. and following)

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

I. GENERAL PRESENTATION

A. THE CLASS ACTION

1. The Applicant wishes to institute a class action on behalf of the following Class, of which he is a Member (the "Class Members"):

« All persons residing in Canada who suffered damages as a result of the implantation of an Inferion Vena Cava Filter, manufactured, marketed, distributed, or sold in whole or in part by the Defendants;

AND

All persons residing in Canada who have suffered damages as a result of the implantation to one of the persons referred to in the preceding paragraph of an Inferion vena cava filter, manufactured, marketed, distributed, or sold in whole or in part by the Defendants, including their spouse, father, mother and other ascendants, children, other parents, legal representatives, other relatives or their estate.»

or such other Class definition as may be approved by the Court;

- 2. This action involves Inferior Vena Cava Filters (hereafter "IVC Filters");
- 3. An IVC Filter is a medical device that is placed in the inferior vena cava intended to trap blood clots and prevent them from passing into the lungs;

- 4. 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, distribution, and sale of their IVC Filters;
- 5. The Defendants misrepresented that their IVC Filters are a safe and effective treatment for blood clots and other thrombolytic events, when in fact this device causes serious injuries and complications as defined in Paragraphs 33 and 34 below;
- 6. The Applicant therefore holds the Defendants responsible for having conceived, researched, developed, tested, manufactured, packaged, labeled, sold, promoted, marketed, distributed and/or marketed IVC Filters, a medical device presenting a serious risk of injury and even a life-threatening one for people in whom it is implanted, without providing adequate warnings against the risks and dangers involved;
- 7. As a result of the Defendants' negligence, the Applicant and the Class Members have suffered personal injuries, damages and pain and suffering, for which they claim compensation;

B. THE DEFENDANTS

- 8. The Defendant Cook Medical Incorporated also known as Cook Medical, Inc., is an American corporation with its head office located in Bloomington, Indiana;
- 9. The Defendant Cook Incorporated, is an American corporation with its head office located in Bloomington, Indiana, and is the parent company of the Defendant Cook Medical Incorporated;
- 10. The Defendant Cook (Canada) Inc., is a Canadian corporation with its head office in Stouffville in Ontario, the whole as it appears from the extract of the State of information from the *Registraire des entreprises du Québec* produced herein as **Exhibit P-1**;
- The Defendant, Cook Group, Inc., is an American corporation with its head office located in Bloomington, Indiana, and is the parent company of the Defendants Cook Medical Incorporated, Cook Incorporated and Cook (Canada) Inc.;
- 12. The Defendant, William Cook Europe ApS, is a Danish entity headquartered in Bjaeverskov, Denmark. William Cook Europe ApS operates as a subsidiary of the Defendant Cook Group Inc.
- 13. Hereinafter, each of the above Defendants shall be collectively referred to as "Cook" (the "Defendants");

- 14. The business of each of the Defendants are 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, IVC Filters in Canada;
- 15. Considering the close links between the Defendants and in light of the foregoing, each Defendants shall be jointly liable for damages caused by the actions and/or omissions of the other.
- 16. At all material times, the Defendants were engaged in the business of designing, manufacturing, testing, packaging, promoting, marketing, distributing, labelling, and/or selling IVC Filters in Canada;
- 17. The development of IVC Filters 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 IVC Filters, and other actions central to the allegations of this lawsuit, were undertaken by the Defendants in Canada and elsewhere;

C. THE DEFENDANTS' IVC FILTERS PRODUCTS

- 18. The Defendants' IVC Filters are medical devices designed to trap blood clots passing through the inferior vena cava;
- 19. The inferior vena cava is a large vein that returns blood from the lower part of the body to the heart;
- 20. Under fluoroscopic guidance, the Defendants' IVC Filters are percutaneously placed (by needle-puncture of the skin) via the jugular or femoral vein;
- 21. In certain individuals, for various reasons, blood clots travel from vessels in the lower body, through the vena cava into the lungs;
- 22. Frequently, such blood clots develop in the deep leg veins and are referred to "deep vein thrombosis":
- 23. Once a blood clot reaches the lungs, it is considered a "pulmonary emboli", a serious thromboembolic event that can even result in death;
- 24. The IVC Filters are intended to prevent blood clots from passing through the IVC and entering the heart and/or lungs;
- 25. Obese patients, surgical patients, individuals who suffer from vascular disease or whom

- have experienced strokes, and individuals who suffer from clotting disorders are at increased risk for developing deep vein thrombosis or pulmonary emboli;
- 26. Many individuals at risk for deep vein thrombosis or pulmonary emboli can use prescription anticoagulants to manage the risk of developing blood clots;
- 27. For individuals at risk for deep vein thrombosis or pulmonary emboli who cannot manage their conditions with medications, physicians may recommend surgically implanting an IVC Filter to prevent thromboembolic events;
- 28. The IVC Filters are made of a cobalt-chromium-nickel alloy ("Conichrome") and are umbrella-shaped with four primary struts for fixation and a second set of eight secondary struts to improve self-centering and clot trapping;
- 29. In or about 2002, the Defendants began marketing and selling a IVC filter in Canada known as Cook Günther Tulip Vena Cava Mreye Filter Set;
- 30. In March 2006, the Defendant Cook (Canada) inc., has received licensing from Health Canada for the *Celect Vena Cava Filter Set*, a "second generation" version of the clinically proven *Günther Tulip Filter Set*, the whole as it appears from the article produced herein as **Exhibit P-2**;
- 31. Therefore, in or about 2006, the Defendants began marketing and selling a product in Canada known as Cook Celect Vena Cava Filter Set;
- 32. In or about 2014, the Defendants began marketing and selling a product in Canada known as Cook Celect Platinum Vena Cava Filter Set;

D. THE CAUSES OF ACTION - PRODUCT LIABILITY

- 1. OBLIGATIONS OF QUALITY AND SECURITY OF THE PRODUCT AND THE RISKS POSED BY IVC FILTERS
- 33. The IVC Filters have high failure, injury, and complication rates, fail to perform as intended, have resulted in deaths, severe and irreversible injuries, conditions, and have caused damages to the Applicant and other Class Members.
- 34. The injuries and complications suffered due to the Defendants' IVC Filters include but are not limited to:

- a. device migration, where the IVC Filter migrates from the deployed position to another part of the inferior vena cava, to the heart, or to the pulmonary outflow tract;
- b. device perforation, where one or more of the Conichrome struts punctures the wall of the inferior vena cava or another vein;
- device fracture, where one or more of the Conichrome struts breaks loose. The strut may travel in the bloodstream and become lodged in another vein or organ;
- d. device embolization, where the entire device or fragments of the device enters the heart or lungs; and
- e. the inability to retrievable the device. After implantation, the body forms a coating around the device called endothelialisation making percutaneous removal of the device difficult or impossible. In such cases, removing the device requires abdominal surgery to reach the inferior vena cava;
- 35. In a retrospective study of all Cook Gunther Tulip Filters and Cook Celect filters retrieved between July 2006 and February 2008 in the United States, researchers found that "unsuccessful retrieval was due to significant endothelialisation and caval penetration" and that "hook endothelialisation is the main factor resulting in failed retrieval and continues to be a limitation with these filters" the whole as it appears from the study produced herein as **Exhibit P-3**;
- 36. In August of 2010, the U.S. Food and Drug Administration ("FDA") warned healthcare professionals about serious complications associated with IVC filters, the whole as it appears from the article produced herein as Exhibit P-4;
- 37. A 2012 study entitled "Perforation of the IVC: rule rather than the exception after longer indwelling times for *Günther Tulip* and *Celect* Retrievable Filters" reported that 100% of the *Cook Günther Tulip* and *Celect* filters imaged after 71 days of implant caused some degree of filter perforation of the venal caval wall, the whole as it appears from the study produced herein as **Exhibit P-5**;
- 38. The same study reported that tilting of the device was seen in 40% of implanted Gunther Tulip and Celect filters;
- 39. A 2013 study published in JAMA International found that while most of the IVC filters it reviewed were designed for retrieval, only 8.5% were successfully removed. "Therefore, approximately 91.5% of retrievable filters placed in patients at risk for VTE [venous thromboembolism] became permanent filters.", the whole as it appears from the study produced herein as **Exhibit P-6**;

- 40. A 2013 study published in the Journal of the American College of Cardiology reported that complication rates of retained filters include filter migration or embolization in up to 69% of cases, and strut facture and penetration of up to 24% of the whole as it appears from the study produced herein as **Exhibit P-7**;
- 41. In May of 2014, the FDA updated its initial findings and mentions that "if the patient's transient risk for pulmonary embolism has passed, the risk/benefit profile begins to favor removal of the IVC filters be removed between 29 and 54 days after implantation.", the whole as it appears from the article produced herein as **Exhibit P-8**;
- 42. This recommendation followed the findings of an October 2013 study which concluded that "the risks of complications start to outweigh the protective benefits of the filter at day 35 post implantation", the whole as it appears from the study produced herein as **Exhibit P-9**;
- 43. The failure of Defendants' IVC Filters is attributable, in part, to the fact that the IVC Filters suffer from a design defect resulting in the inability to withstand the normal anatomical and physiological loading cycles exerted *in vivo*;
- 44. The IVC Filters 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;
- 45. The IVC Filters 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 IVC Filters;
- 46. The Defendants failed to adequately test their IVC Filters in a manner that would fully disclose the magnitude of the risks associated with their use;
- 47. The Defendants failed to conduct any adequate follow-up studies or any adequate long-term studies on the efficiency, the safety and the risks related to their IVC Filters;
- 48. Despite the Defendants' knowledge of the injuries, caused by their IVC Filters, the Defendants have, and continue to, manufacture, market, and sell their IVC Filters, while failing to adequately warn, label, instruct, and disseminate information with regard to their IVC Filters, both prior to and after the marketing and sale of their IVC Filters;

2. DUTY OF CARE AND TO INFORM ABOUT THE RISKS POSED BY IVC FILTERS

49. Contrary to the representations made to the medical community, and ultimately to the patients themselves, the Defendants knew or ought to have known, with respect to the

available scientific knowledge, that their IVC Filters were defective, and were not properly manufactured to withstand normal, foreseeable, and intended use;

- 50. At all material times, Defendants owed a duty of care to the Applicant to:
 - a. ensure that their IVC Filters were fit for their intended and/or reasonably foreseeable use;
 - conduct appropriate testing to determine whether and to what extent use of their IVC Filters posed serious health risks, including the magnitude of risk of developing injuries and complications;
 - c. properly, adequately, and fairly warn the Applicant and physicians of the magnitude of the risk of developing injuries and complications with use of their IVC Filters compared to alternative treatments;
 - d. ensure that physicians were kept fully and completely warned and informed regarding all risks associated with their IVC Filters;
 - e. monitor, investigate, evaluate and follow up on adverse reactions to the use of their IVC Filters; and
 - f. properly inform Health Canada and other regulatory agencies of all risks associated with their IVC Filters.
- 51. The Defendants knew or should have known that the risks of using their IVC Filters included severe injuries and complications;
- 52. The Defendants knew or should have known that their IVC Filters were unsafe, defective, unreasonably dangerous, and not fit for their intended purposes;
- 53. The Defendants, through its representatives and agents, negligently, recklessly and/or carelessly marketed, distributed and/or sold their IVC Filters without adequate warnings of the products' serious side effects and unreasonably dangerous risks;
- 54. The Defendants, through their representatives and agents, failed to adequately warn physicians and consumers, including the Applicant and the Class Members, of the risk of injuries and complications caused by their IVC Filters;
- 55. The Defendants did not provide adequate safety data to Health Canada with respect to their IVC Filters;
- 56. The Defendants have consistently underreported and withheld information about the propensity of their IVC Filters to fail and cause injuries and complications, and have misrepresented the efficacy and safety of their IVC Filters through various means and

- media, misleading Health Canada, the medical community, patients, and the public at large;
- 57. The Defendants, after noticing problems with their IVC Filters, failed to issue adequate warnings, timely recall their IVC Filters, publicize the problems and otherwise act properly and in a timely manner to alert the public, including adequately warning the Applicant and his physicians of their IVC Filters inherent risks;
- 58. The Defendants failed to timely cease the manufacturing, marketing and/or distribution of their IVC Filters when they knew or ought to have known that their IVC Filters caused injuries and complications;
- 59. The Defendants failed to conform with applicable disclosure and reporting requirements pursuant to products safety and health regulations;
- 60. Rather, the Defendants specifically advertise the Conichrome construction of the filter as a frame which "reduces the risk of fracture";
- 61. The IVC Filters are designed to be permanent or optionally retrievable, meaning that the device may be surgically removed using the tiny hook at the top of the device. The Defendants specifically advertise their design as "remarkably easy to retrieve";
- 62. The Defendants' IVC Filters have been and continue to be marketed to the medical community, and in turn to patients, as safe, effective, reliable medical devices, to prevent, among other things, recurrent pulmonary embolism via placement in the inferior vena cava;
- 63. The Defendants have marketed and sold their IVC Filters to the medical community at large, and in turn to patients, through carefully planned, multifaceted marketing campaigns and strategies;
- 64. These campaigns and strategies include aggressive marketing to health care providers at medical conferences, hospitals, and private offices;
- 65. The Defendants also utilize brochures and websites offering misleading expectations as to the safety and utility of their IVC Filters;
- 66. In all of the circumstances of this case, the Defendants applied callous and reckless disregard for the health and safety of the Applicant and Class Members, therefore breaching their duties of security and information;

3. FAULT

- 67. The Defendants' IVC Filters were defective because they are unreasonably dangerous, beyond the dangers which could reasonably have been contemplated by the Applicant, Class Members, or their physician;
- 68. Any benefit from using the IVC Filters was outweighed by the serious and undisclosed risks of their use when used as the Defendants intended;
- 69. There are no individuals for whom the benefits of the IVC Filters outweigh the risks, given that there are many alternative products and procedures that are at least as efficacious as the IVC Filters and carry far less and/or less serious risks than the IVC Filters;
- 70. In any case, the Defendants' actions constitutes a wrongful misconduct, engaging their responsibility under the *Québec civil Code* and the *Consumer protection act*;

4.CAUSATION

- 71. The damages sustained by the Applicant and the Class Members are an immediate and direct consequence of the Defendants' negligence, as they failed to ensure that their IVC Filters were not dangerous to recipients during the course of their use and that they were fit for their intended purpose and of merchantable quality;
- 72. The risks associated with use of the IVC Filters, including injuries and complications in all persons receiving their IVC Filters, were in the exclusive knowledge and control of the Defendants;
- 73. The extent of the risks were not known to, and could not have been known by the Applicant and the Class Members;
- 74. The Applicant's injuries would not have occurred but for the negligence of the Defendants in failing to ensure that their IVC Filters were safe for use or, in the alternative, for failing to provide an adequate warning of the risks associated with using their IVC Filters to the Applicant and the Class Members, and to their physicians;

E. <u>DAMAGES</u>

- 75. The Applicant and the Class Members' injuries and damages were caused by the negligence of the Defendants, its representatives, affiliates, and agents.
- 76. As a result of the Defendant's negligence, the Applicant has suffered and continue to suffer serious personal injuries and pain and suffering.

- 77. As a result of the conduct of the Defendants, the Applicant and the Class Members suffered and continue to suffer expenses and damages, of a nature and amount to be determined at trial:
- 78. The Applicant and the Class Members are entitled to claim damages in compensation for their bodily, moral and material injuries such as, but not being limited to:
 - a. Future and past loss of income;
 - b. Future and past medical expenses;
 - c. Future and past material expenses
 - d. Pain and suffering;
- 79. The Applicant also claims punitive damages for the reckless and unlawful conduct of the Defendants.

II. FACTS GIVING RISE TO THE APPLICANT'S CLAIM

- 80. The Applicant, Patrick Thomas Wallace, is individual residing in Montréal, Canada.
- 81. He is divorced;
- 82. He was implanted with one of the Defendants IVC Filters in March, 2015 at Hôpital du Sacré-Coeur in Montreal;
- 83. He was implanted with the IVC Filter after a history of pulmonary complications and developing deep vein thrombosis (DVT) in both legs;
- 84. He was told that the purpose of the IVC was to prevent the blood clots in his legs from travelling to his lungs;
- 85. Before and after the surgery was on Coumadin to prevent the development of blood clots;
- 86. Since being implanted with the device, he has experienced pain near implantation site, shortness of breath, and dizziness;
- 87. Later in 2015 his physician has attempted to retrieve the IVC filter at Hôpital du Sacré-Coeur in Montreal;
- 88. The retrieval procedure was done under conscious sedation through his jugular vein;
- 89. The Physician being unable to successfully remove the IVC filter, he was told it was stuck;
- 90. He describes the attempted retrieval procedure as extremely painful;

- 91. Since the attempted retrieval, he reports that he feels constant pain where the IVC filter is implanted;
- 92. He had an appointment on March 22nd 2016 with his radiologist;
- 93. At the time of filing, he has another appointment on April 8, 2016, to discuss the possibility of removing the IVC filter;
- 94. He is fearful that if he does not have the filter removed, it may fracture or migrate causing more complications. His preference is to have it removed;

III. FACTS GIVING RISE TO THE PERSONAL CLAIM OF EACH MEMBER OF THE CLASS:

- 95. Each Class Member has been implanted with an IVC Filter or is a relative of a user;
- 96. None of the Class Members has been advised by the Defendants that the implantation of an IVC Filter presented serious risks including severe injuries, which could even lead to death, arising from the complications described here above;
- 97. Each Class Member is entitled to make a claim for damages from bodily, moral and material injuries suffered as a result of the implantation of an IVC Filter marketed by the Defendants, as well as for punitive damages, if applicable.

IV. CONDITIONS REQUIRED TO INSTITUTE A CLASS ACTION

- 98. The composition of the Class makes it difficult or impracticable to apply the rules for mandates to take part in judicial proceedings on behalf of others or for consolidation of proceedings, with respect to provision 575 (3) of the *Code of civil procedure*, for the following reasons:
 - a. The Applicant is unaware of the precise number of people who have had the implantation of an IVC Filter, which are distributed throughout Canada, including the Province of Quebec;
 - b. The number of persons included in the Class cannot be precisely established by the Applicant but could represent hundreds of persons;
 - c. The Applicant does not know and cannot know the identity of the people who have had the implantation of an IVC Filter, especially since medical records are confidential;
 - d. The names and addresses of persons included in the Class are not known to the Applicant;

- e. It is difficult, if not impossible, to find each and every one of those involved in this action and to contact each member to obtain mandates to take part in judicial proceedings on behalf of others or for consolidation of proceedings;
- 99. The claims of the Class Members raise identical, similar or related questions of fact or law, namely:
 - a. Does the implantation of an IVC Filter cause an increase in the risk of severe injuries and complications?
 - b. Have the Defendants been negligent or have the Defendants breached duties of care, security and information which they are responsible for as manufacturers, sellers, importers, distributors of IVC Filters and/or for having marketed these products in the Province of Quebec and elsewhere, under the Québec civil Code and/or the Consumer protection act?
 - c. Are the Class Members entitled to claim damages for bodily, moral and material injuries and punitive damages related to the implantation of an IVC Filter?
 - d. Are the Defendants required to compensate persons who are not themselves users of an IVC Filter, but have suffered damages as a result of the use of these products by their spouse, father, mother and other ascendants, children, other parents, legal representatives, other relatives or their estate?
 - e. If so, what is the nature of the damages that should be compensated, including: pain and suffering, loss of support, any other direct damages?
- 100. The interests of justice weigh in favour of this motion being granted in accordance with its conclusions.

V. NATURE OF THE ACTION AND CONCLUSIONS SOUGHT

- 101. The action that the Applicant wishes to institute for the benefit of the Class Members is an action in damages;
- 102. The conclusions that the Applicant wishes to introduce by way of an application to institute proceedings are:

GRANT the Applicant's action against the Defendants;

CONDEMN Defendants to pay to the Class Members:

- compensatory damages for each person implanted with one of the Defendants' IVC Filters (as defined herein) for their bodily, moral and material injuries such as, but not being limited to:
 - a. Future and past losses of income;
 - b. Future and past medical expenses;
 - c. Future and past material expenses
 - d. Pain and suffering;

or as aggregated following a trial on the common issues;

- punitive damages in an amount to be established by this court following a trial on the common issues
- the costs of distributing all monies received to Class Members;

or such other sum as this Court finds appropriate for all monetary losses;

GRANT the class action of the Applicant on behalf of all the Class Members;

ORDER the treatment of individual claims of each Class Member in accordance with Articles 599 to 601 C.C.P.;

THE WHOLE with interest and additional indemnity provided for in the *Civil Code of Quebec* and with full costs and expenses including expert fees and notice expenses;

- 103. The Applicant suggests that this class action be exercised before the Superior Court in the District of Montréal for the following reasons:
 - a. He resides in the District of Montreal:
 - b. Applicant's counsels have an office in Montreal;
- 104. The Applicant, who is requesting to obtain the status of representative, will fairly and adequately protect and represent the interest of the Class Members for the following reasons:
 - a. The Applicant has been implanted with one of the Defendants' IVC Filters;
 - b. He suffered and still suffers damages following the implantation;

- c. He understands the nature of the action;
- He is available to dedicate the time necessary for an action to collaborate with the Class Members; and
- e. His interests is not antagonistic to those of other Class Members.

105. The present motion is well-founded in fact and in law.

FOR THESE REASONS, MAY IT PLEASE THE COURT:

GRANT the present motion;

AUTHORIZE the bringing of a class action in the form of a motion to institute proceedings in damages;

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

« All persons residing in Canada who have suffered damages as a result of the implantation of an Inferion Vena Cava Filter, manufactured, marketed, distributed, or sold in whole or in part by the Defendants;

AND

All persons residing in Canada who have suffered damages as a result of the implantation to one of the persons referred to in the preceding paragraph of an Inferion vena cava filter, manufactured, marketed, distributed, or sold in whole or in part by the Defendants, including their spouse, father, mother and other ascendants, children, other parents, legal representatives, other relatives or their estate.»

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

- a. Does the implantation of an IVC Filter cause an increase in the risk of severe injuries and complications?
- b. Have the Defendants been negligent or have the Defendants breached duties of care, security and information which they are responsible for as manufacturers, sellers, importers, distributors of IVC Filters and/or for having marketed these products in the Province of Quebec and elsewhere?
- c. Are the Class Members entitled to claim for bodily, moral and material injuries and punitive damages related to the implantation of an IVC Filter?

- d. Are the Defendants required to compensate persons who are not themselves users of an IVC Filter, but have suffered damages as a result of the use of these products by their spouse, father, mother and other ascendants, children, other parents, legal representatives, other relatives or their estate?
- e. If so, what is the nature of the damages that should be compensated, including: pain and suffering, loss of support, any other direct damages?

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

GRANT the Applicant's action against the Defendants:

CONDEMN Defendants to pay to the Class Members:

- compensatory damages for each person implanted with one of the Defendants' IVC Filters (as defined herein) for their bodily, moral and material injuries such as, but not being limited to:
 - a. Future and past loss of income;
 - b. Future and past medical expenses:
 - c. Future and past material expenses
 - d. Pain and suffering;

or as aggregated following a trial on the common issues;

- punitive damages in the amount in an amount to be established by this court following a trial on the common issues
- the costs of distributing all monies received to Class Members;

or such other sum as this Court finds appropriate for all monetary losses;

GRANT the class action of the Applicant on behalf of all the Class Members;

ORDER the treatment of individual claims of each Class Member in accordance with articles 599 to 601 C.C.P.;

THE WHOLE with interest and additional indemnity provided for in the *Civil Code of Quebec* and with full costs and expenses including expert fees and notice expenses;

DECLARE that all Class Members that have not requested their exclusion from the Class in the prescribed delay to be bound by any judgement to be rendered on the class action to be instituted;

FIX the delay of exclusion at 30 days from the date of the publication of the notice to the Class Member;

ORDER the publication of a notice to the Class Member in accordance with article 576 C.C.P.;

THE WHOLE with all legal costs.

Montreal, March 22nd, 2016

Karim Diallo, lawyer

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Lawyers for the Applicant

SUMMONS

(Articles 145 and following C.c.p.)

Filing of a judicial application

Take notice that the Applicant has filed this Application for Authorization to Institute a Class Action and to Appoint the Status of Representative Plaintiff in the office of the Superior Court in the judicial district of Montreal.

Defendants' answer

You must answer the application in writing, personally or through a lawyer, at the courthouse of Montreal situated at 1 Rue Notre-Dame Est, Montréal, Québec, H2Y 1B6, within 15 days of service of the Application or, if you have no domicile, residence or establishment in Québec, within 30 days. The answer must be notified to the Applicant's lawyer or, if the Applicant is not represented, to the Applicant.

Failure to answer

If you fail to answer within the time limit of 15 or 30 days, as applicable, a default judgement may be rendered against you without further notice and you may, according to the circumstances, be required to pay the legal costs.

Content of answer

In your answer, you must state your intention to:

- negotiate a settlement;
- propose mediation to resolve the dispute;
- defend the application and, in the case required by the Code, cooperate with the
 Applicant in preparing the case protocol that is to govern the conduct of the proceeding.
 The protocol must be filed with the court office in the district specified above within 45
 days after service of the summons or, in family matters or if you have no domicile,
 residence or establishment in Québec, within 3 months after service;
- propose a settlement conference.

The answer to the summons must include your contact information and, if you are represented by a lawyer, the lawyer's name and contact information.

Change of judicial district

You may ask the court to refer the originating Application to the district of your domicile or residence, or of your elected domicile or the district designated by an agreement with the plaintiff.

If the application pertains to an employment contract, consumer contract or insurance contract, or to the exercise of a hypothecary right on an immovable serving as your main residence, and if you are the employee, consumer, insured person, beneficiary of the insurance contract or hypothecary debtor, you may ask for a referral to the district of your domicile or residence or the district where the immovable is situated or the loss occurred. The request must be filed with the special clerk of the district of territorial jurisdiction after it has been notified to the other parties and to the office of the court already seized of the originating application.

Transfer of application to Small Claims Division

If you qualify to act as a plaintiff under the rules governing the recovery of small claims, you may also contact the clerk of the court to request that the application be processed according to those rules. If you make this request, the plaintiff's legal costs will not exceed those prescribed for the recovery of small claims.

Calling to a case management conference

Within 20 days after the case protocol mentioned above is files, the court may call you to a case management conference to ensure the orderly progress of the proceeding. Failing this, the protocol is presumed to be accepted.

Exhibits supporting the application

In support of the Application for Authorization to Institute a Class Action and to Appoint the Status of Representative Plaintiff, the Applicant intends to use the following exhibits:

- Exhibit P-1: Extract of the State of information from the Registraire des entreprises du Québec;
- Exhibit P-2: Release dated March 14, 2006 from Cook Group Incorporated entitled "Cook Canada Receives Approval for Next-Generation CelectTM Vena Cava Filter";
- Exhibit P-3: Study published in 2009 entitled "Assessment of Snared-Loop Technique When Standard Retrieval of Inferior Vena Cava Filters Fails";
- Exhibit P-4: Article of August 2010 from the U.S. Food and Drug Administration and entitled "Inferior Vena Cava (IVC) Filters: Initial Communication: Risk of Adverse Events with Long Term Use";
- Exhibit P-5: Study of 2012 entitled "Perforation of the IVC: rule rather than the exception after longer indwelling times for *Günther Tulip and Celect Retrievable Filters*";
- Exhibit P-6: Study of 2013 published in JAMA International and entitled "Indications, Complications, and Management of Inferior Vena Cava Filters";

- Exhibit P-7: Study of 2013 published in the Journal of the American College of Cardiology and entitled "Inferior Vena Cava Filters";
- Exhibit P-8: Article of May 2014 from the U.S. Food and Drug Administration and entitled "Removing Retrievable Inferior Vena Cava Filters: FDA Safety Communication";
- Exhibit P-9: Study of October 2013 from the Journal of Vascular Surgery and entitled "Decision analysis of retrievable inferior vena cava filters in patients without pulmonary embolism".

These exhibits are available on request.

Notice of presentation of an application

If the application is an application in the course of a proceeding or an application under Book III, V, excepting an application in family matters mentioned in article 409, or VI of the Code, the establishment of a case protocol is not required; however, the application must be accompanied by a notice stating the date and time it is to be presented.

Montreal, March 22nd, 2016

Karim Diallo, lawyer

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SISKINDS DESMEULES AVOCATS s.e.n.c.r.l.

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Seskinds, Desmeules, avocats, S.E.N.C.R.L.

Lawyers for the Applicant

NOTICE OF PRESENTATION (Articles 146 and 574 al. 2 C.P.C.)

To:

COOK MEDICAL INCORPORATED, doing business under COOK MEDICAL INC., 400 Daniels Way, Bloomington, Indiana, 47404, United States

And

COOK INCORPORATED

750 Daniels Way, Bloomington, Indiana, 47404, United States

And

COOK (CANADA) INC.

165 Mostar Street, Stouffville, Ontario, L4A 0Y2, Canada

And

COOK GROUP INC.

750 Daniels Way, P.O. Box 1608 Bloomington, Indiana, 47402, United States

And

WILLIAM COOK EUROPE APS

Sandet 6, 4632 Bjaeversok, Danemark

TAKE NOTICE that the present Application For Authorization To Institute A Class Action and to Obtain the Status of Representative Plaintiff will be presented before this Honourable Court, at the Palais de justice, located at 1, Notre-Dame Street East, in the City and Disctrit of Montreal, on the date set by the coordinator of the class actions chamber.

PLEASE ACT ACCORDINGLY.

Montreal, March 22nd, 2016

Siskinds Desmeules, avocats, S.E.N.C.R.L.
Karim Diallo, lawyer

karim.diallo@siskindsdesmeules.com

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Lawyers for the Applicant

PROVINCE OF QUEBEC CANADA SUP---- COLIDE ICL ASS ACTION) DISTRICT OF MONTREAL 500-06-000784-161

PATRICK WALLACE

APPLICANT;

business under COOK MEDICAL INC.) COOK GROUP INC. COOK (CANADA) INC. COOK INCORPORATED COOK MEDICAL INCORPORATED (doing

Defendants.

WILLIAM COOK EUROPE APS

APPOINT THE STATUS OF REPRESENTATIVE PLAINTIFF, SUMMONS APPLICATION FOR AUTHORIZATION TO INSTITUTE A CLASS ACTION AND TO AND NOTICE OF PRESENTATION

ORIGINALE

BB-6852

SISKINDS, DESMEULES ANDCARS

Tél.: (418) 694-2009 Tél.: (418) 694-0281 Les Promenades du Vieux-Québec 43 rue de Buade, bureau 320 Québec, (Québec) GIR 4A2 www.siskinds.com

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N/D: 67-182 Me Karim Diallo