NO. *Court File No.* ***VLC-S-S-235885***
VANCOUVER REGISTRY

**IN THE SUPREME COURT OF BRITISH COLUMBIA**

BETWEEN:

ETHAN RIBALKIN

PLAINTIFF

AND:

CARTIVA, INC., STRYKER CANADA ULC,
and WRIGHT MEDICAL TECHNOLOGY CANADA ULC

DEFENDANTS

**Brought pursuant to the *Class Proceedings Act*, R.S.B.C. 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.

**Part 1: STATEMENT OF FACTS**

The Parties

1. The plaintiff is a mortgage broker. For the purposes of this action, the plaintiff's address for service is Suite 2020 – 650 West Georgia Street, Vancouver, British Columbia.

2. The defendant, Cartiva, Inc., is, and at all times relevant to this action was, a corporation with its principal place of business and headquarters located at 6120 Windward Parkway, Suite 220, Alpharetta, Georgia, USA, 30005.

3. The defendant, Stryker Canada ULC, is, and at all times relevant to this action was, a company duly formed under the law of the Province of British Columbia, with its registered and records office address of 1500 Royal Centre, 1055 West Georgia Street, Vancouver, British Columbia.

4. The defendant, Wright Medical Technology Canada ULC is, and at all times relevant to this action was, a company duly formed under the law of the Province of British Columbia, with its registered and records office address of 1500 Royal Centre, 1055 West Georgia Street, Vancouver, British Columbia.

5. At all times material, Cartiva, Inc., Stryker Canada ULC, and Wright Medical Technology Canada ULC, are hereinafter referred to collectively as "Stryker" or the "defendants", developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the defective product under the name Cartiva® Synthetic Cartilage Implant ("SCI") (hereinafter referred to as "Cartiva" or the "defective device"), either directly or indirectly, to members of the general public within Canada, including the plaintiff.

6. 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, labeling, and/or selling for a profit, either directly or indirectly through an agent, affiliate or subsidiary, Cartiva in Canada.

7. At all material times, the defendants were engaged in the business of researching, designing, manufacturing, developing, preparing, processing, inspecting, testing, packaging, promoting, marketing, distributing, labeling, importing, and/or selling Cartiva in Canada.

8. The plaintiff brings this claim on behalf of himself and on behalf of a proposed class of similarly situated persons who were implanted with Cartiva in British Columbia and elsewhere in Canada. The proposed class will be further defined in the plaintiff's application for certification.

The Defective Product

9. The Cartiva implant is intended to treat first metatarsophalangeal joint osteoarthritis (also known as big toe arthritis). Cartilage is a specialized tissue responsible for mediating contact between bones on surfaces with relative movement. As osteoarthritis deteriorates joint cartilage in the first metatarsophalangeal joint ("MTP"), a person loses the protective cushion of joint cartilage, which causes extremely painful bone-on-bone rubbing. Since cartilage is not vascularized, it does not restore itself or recover quickly from injury.

10. This condition has been surgically treated with arthrodesis (also known as "fusion"), or a Cartiva implant, which is intended to act like a cushion to prevent bone-on-bone pain.

11. Arthrodesis is a procedure in which the phalangeal and metatarsal bones are cut and shaped to fit together to relieve toe joint pain. The two bones are then aligned, set at a predetermined angle, and permanently fixed with either screws and/or a plate so the two bones "fuse" together permanently. A typical fusion procedure eliminates the ability to move the first joint of the big toe.

12. In contrast to arthrodesis, the Cartiva implant is a molded cylindrical implant that is placed into the metatarsal head in the first metatarsophalangeal joint via press-fit implantation using instruments specifically designed for placement of the device. The Cartiva instrumentation is used to drill an appropriately sized cavity in the metatarsal head and deploy the Cartiva implant into the prepared cavity.

13. The defendants allege joint repair with a Cartiva implant is simple, does not require significant removal of healthy tissue, and typically results in nominal surgical trauma and rapid recovery.

14. The defendants promoted and sold Cartiva through carefully planned marketing campaigns and strategies, which included aggressively marketing Cartiva to the

medical community and public as a safe, effective, and reliable medical device that was more effective than traditional products and procedures for the treatment of hallux rigidus or hallux limitus. For example, Cartiva promotional materials from 2018 include the following claims:

a. Cartiva is a long-term treatment.
b. There have been limited cases where the Cartiva was removed because a patient still had pain in their big toe joint.
c. Only nine out of every 100 Cartiva subjects had the device removed within two years after surgery.

15. Contrary to the defendants' representations, clinically, Cartiva demonstrates a high failure and complication rate, resulting in high rates of failure and necessary reoperations and the studies the defendants rely on are not reliable.

16. Cartiva failures have caused severe and irreversible patient injuries, including, but not limited to, subsidence, recurrence, chronic pain, scarring, infection, and the need for further invasive surgeries.

17. The risks associated with Cartiva, which were known to the defendants at all material times, have not been adequately communicated to patients, physicians, hospitals, or the medical community. The defendants have failed to warn of the frequency, seriousness, and predictability of the complications caused by Cartiva. Cartiva creates risks to the health and safety of patients that are more significant than the risks posed by other products and procedures available to treat big toe arthritis and which outweigh the utility of Cartiva. Furthermore, the defendants failed to provide adequate safety data to Health Canada with respect to Cartiva. The defendants knew or ought to have known that Cartiva was unsafe, defective, unreasonably dangerous, and not fit for its intended purpose. If the risks associated with Cartiva were appropriately and fully disclosed, patients such as the plaintiff would have chosen alternative treatment options.

The Plaintiff

18. The plaintiff underwent surgery in February 2021, in which he received a Cartiva implant. The surgery was conducted without complications and the plaintiff followed medical advice during the recovery period.

19. In approximately September 2021, it was determined that the plaintiff's Cartiva had failed and the plaintiff required a further invasive surgery including the removal of the Cartiva and arthrodesis, which took place in 2022.

20. The implantation and failure of the Cartiva has had a devastating impact on the plaintiff, leaving him with permanent injuries including, but not limited to, chronic pain and functional limitations, and interfering with all aspects of his domestic, social, recreational, and vocational endeavors. The plaintiff has incurred, and will

continue to incur, loss of employment income, cost of medical care, and out of pocket expenses.

21. The plaintiff's complications and further surgery directly and proximately resulted from the defective and dangerous condition of the Cartiva. The plaintiff was not provided adequate warnings prior to being implanted with Cartiva. If he had been aware of the risks, the plaintiff would not have agreed to be implanted with this defective device.

**Part 2: RELIEF SOUGHT**

1. The plaintiff claims on his behalf and on behalf of a class of similarly situated persons:

    a. An order certifying this action as a class proceeding and appointing him as representative plaintiff under the *Class Proceedings Act*;

    b. General damages;

    c. Special damages;

    d. Loss of earning capacity, both past and future;

    e. Cost of future care;

    f. Aggravated damages;

    g. Punitive damages;

    h. Declaratory and injunctive relief as well as statutory damages under the *Business Practices and Consumer Protection Act,* S.B.C. 2004, c. 2;

    i. Recovery of health care costs incurred by the Ministry of Health Services on their behalf pursuant to the *Health Care Costs Recovery Act*, S.B.C. 2008, c. 27;

    j. Interest pursuant to the *Court Order Interest Act*, [RSBC 1996] Chapter 79 and amendments thereto;

    k. Costs; and,

    l. Such further and other relief as this Honourable Court may deem meet and just.

## Part 3: LEGAL BASIS

### Negligence

1. As the designers, manufacturers, developers, preparers, processers, inspectors, testers, packagers, promoters, marketers, distributors, labelers, importers, and/or sellers of Cartiva, the defendants were in such close and proximate relationship to the plaintiff and other class members so as to owe them a duty of care. The defendants caused Cartiva to be introduced into the stream of commerce at a time when they knew that any defects in Cartiva would cause foreseeable injury to the plaintiff and class members.

2. The defendants owed a duty to the plaintiff and class members to exercise reasonable care when researching, designing, manufacturing, developing, preparing, processing, inspecting, testing, packaging, promoting, marketing, distributing, labeling, importing, and/or selling Cartiva. The defendants breached the standard of care expected in the circumstances.

3. The defendants had a duty to the plaintiff and class members to disclose and warn of the defective nature of Cartiva because the defendants were in a superior position to know the safety and efficacy of Cartiva.

4. The plaintiff has sustained damages, loss and expense in consequence of the negligence of the defendants, particulars of which include, but are not limited to:

    a. Selling, marketing, and promoting Cartiva as a safe option when they knew or ought to have known of its risks and significant failure rate;

    b. Failing to perform adequate testing or clinical trials of Cartiva;

    c. Failing to adjust the production method or combining PVA with other materials to produce a more suitable and stable material than the current design;

    d. Failing to design or manufacture Cartiva safely or in such a manner that rendered it sufficiently safe for its intended purpose;

    e. Failing to conduct an adequate and timely analysis of adverse event reports;

    f. Misrepresenting the purported benefits and safety of Cartiva and its associated risks;

    g. Failing to adequately educate their sales representatives and physicians regarding the risks associated with Cartiva;

h. Misrepresenting the safety and efficacy of Cartiva;

i. Relying on studies to support the safety and efficacy of Cartiva when they knew or ought to have known about the shortcomings of such studies;

j. Failing to instruct their employees to accurately and candidly disclose consumer complaints and complications associated with Cartiva to Health Canada in a timely manner, or at all;

k. Failing to warn consumers, their health providers, and Health Canada of the complications presented by Cartiva;

l. Failing to provide proper long-term investigations of the effects and risks of Cartiva;

m. Failing to recall Cartiva in a timely manner;

n. Failing to provide effective, complete, and clear training and information to physicians;

o. Marketing Cartiva, which was unsafe, not fit for its intended purpose, and not of merchantable quality;

p. Failing to design and implement an appropriate post-marketing surveillance system to monitor and identify the complications associated with Cartiva;

q. Placing Cartiva on the market when the defendants knew or ought to have known its potential complications outweighed any potential benefits; and,

r. Failing to ensure that Cartiva was not dangerous to recipients during the course of their use and that they were fit for their intended purpose and of merchantable quality;

s. Failing to adequately test Cartiva in a manner that would fully disclose the magnitude of the risks associated with its use, including, but not limited to, the injuries, loss, and damage sustained by the plaintiff and class members;

t. Unreasonably and carelessly designing a product that was insufficient to withstand the foreseeable use of normal placement within the human body;

u. Failing to conduct any or any adequate follow-up or long-term studies on Cartiva's efficacy, safety, and risks;

v. Failing to issue adequate warnings about problems with Cartiva, implement a timely recall of Cartiva, promptly publicize the problems with Cartiva, and otherwise act properly and in a timely manner, to alert the public and other health care providers of Cartiva inherent dangers;

w. Such further particulars as will be shown at trial.

5. The plaintiff pleads the provisions of the *Negligence Act*, R.S.B.C. 1996 c. 333 and amendments thereto.

6. The defendants are vicariously liable for the acts and omissions of their officers, directors, agents, employees, and representatives.

**Business Practices and Consumer Protection Act**

7. In its sales brochures, advertisements, and other forms of representations to the public, the defendants made statements concerning the safety of Cartiva that had the capability, tendency, or effect of deceiving or misleading customers.

8. These representations as to the safety of Cartiva were untrue, deceptive, and misleading and as a result constituted deceptive and unconscionable acts. The plaintiff pleads and relies upon the provisions of the *British Columbia Business Practices and Consumer Protection Act*, S.B.C. 2004, c. 2.

**Sale of Goods Act**

9. At all relevant times, the defendants knew the intended use of Cartiva.

10. The plaintiff relied upon the defendants' representations and recommendations in using Cartiva.

11. It was an express and an implied condition of the contract of purchase and sale that Cartiva would be reasonably fit for its intended purpose and of merchantable quality.

12. Cartiva was unfit for its intended purpose and not of merchantable quality.

13. The plaintiff relies on and pleads the provisions of the *Sale of Goods Act*, R.S.B.C. 1996, c. 410 and amendments thereto, including, but not limited to, sections 17 and 18.

**Regulatory Duties**

**14.** The plaintiff pleads and relies upon the *Food and Drugs Act*, R.S.C. 1985, c. F-27; and *The Medical Devices Regulations*, SOR/98-282, which were breached by the defendants.

**Causation and Damages**

15. As a result of the defendants' negligence, breach of the *British Columbia Business Practices and Consumer Protection Act*, breach of the *Sale of Goods Act*, and breach of regulatory duties, the plaintiff and class members have suffered and will continue to suffer injury, loss, and damage. Such injury, loss, and damage were foreseeable by the defendants. Particulars of the injury, loss, and damage by the plaintiff and class members which were caused or materially contributed to by the aforementioned acts of the defendants include, but are not limited to:

    a. Personal injury;
    b. Special damages for medical expenses and out of pocket expenses;
    c. Loss of both past and future income; and,
    d. Cost of future care.

16. The conduct of the defendants as hereinbefore set out showed reckless disregard for the well-being of the public, the plaintiff, and class members. The defendants' negligence was callous and arrogant and offends the ordinary community standards of moral and decent conduct. The actions, omissions, or both, of the defendants involved such want of care as could only have resulted from actual conscious indifference to the rights, safety, or welfare of the plaintiff and class members. Accordingly, the plaintiff, on his own behalf and on behalf of the class members, claims aggravated and punitive damages.

**Health Care Costs Recovery**

17. The plaintiff is a beneficiary as defined in section 1 of the *Health Care Costs Recovery Act*, SBC 2008 c.27 (the "*HCCRA*") who has received health care services as defined in section 2(1) of the *HCCRA* and who claims for the past cost and future cost of health care services required as a result of the negligence of the defendants pursuant to section 3 of the *HCCRA*.

**Plaintiff's address for service:**

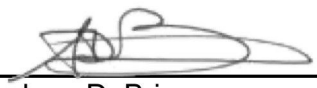
Murphy Battista LLP
Barristers and Solicitors
Suite 2020 – 650 West Georgia Street
Vancouver, B.C.
Canada V6B 4N7

**Fax number address for service:** 604-683-5084

**Place of trial:** Vancouver, British Columbia

**The address of the registry is:** 800 Smithe Street, Vancouver, B.C., V6Z 2E1

Dated: 24/Aug/2023



Andrew D. Brine,
Lawyer for the plaintiff

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 action is brought pursuant to the *Class Proceedings Act* for injury, loss, and damage suffered by the plaintiff and other class members as a result of the defendants' negligence and breach of duty related to the Cartiva implant issued and sold from 2005 to the present date in British Columbia and elsewhere in Canada.

### 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:

*Negligence Act*, R.S.B.C. 1996, c. 333
*Sale of Goods Act*, R.S.B.C. 1996, c. 410
*Food and Drugs Act*, R.S.C. 1985, c. F-27
*Business Practices and Consumer Protection Act*, S.B.C. 2004, c. 2