

COURT FILE No.

ONTARIO SUPERIOR COURT OF JUSTICE

BETWEEN:

CLARENCE RENAUD

PLAINTIFF

- AND -

ZIMMER DENTAL MEDICAL INCORPORATED, BIOGENICS INC., MEDTRONIC OF CANADA LTD., MENTOR MEDICAL SYSTEMS (CANADA) INC., BIOHORIZON.COM INCORPORATED, LASSWELL MEDICAL CO. LTD., MEDTRONIC SOFAMOR DANEK USA INC., SPINALGRAFT TECHNOLOGIES LLC, REGENERATION TECHNOLOGIES INC., BIOMEDICAL TISSUE SERVICES LTD., MICHAEL MASTROMARINO AND JOSEPH NICELLI

DEFENDANTS

PROCEEDING UNDER THE *CLASS PROCEEDINGS ACT*, 1992.

STATEMENT OF CLAIM

TO THE DEFENDANTS

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

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

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

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

IF YOU FAIL TO DEFEND THIS PROCEEDING, JUDGMENT MAY BE GIVEN AGAINST YOU IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU.

If you wish to defend this proceeding but are unable to pay legal fees, legal aid may be available to you by contacting the Legal Aid Office.

DATE: _____

ISSUED BY:

REGISTRAR

**ADDRESS OF
COURT OFFICE:**

**245 Windsor Avenue
Windsor, Ontario
N9A 1J2**

TO: Zimmer Dental Medical Incorporated
2323 Argentia Road
Mississauga, Ontario
L5N 5N3

AND TO: Biogenics Inc.
21-7 Amber Street
Markham, Ontario
L3R 4Z3

AND TO: Medtronic of Canada Ltd.
100 King Street West
Suite 1600
First Canadian Place
Toronto, Ontario
M5X 1G5

AND TO: Mentor Medical Systems (Canada) Inc.
1129 Wentworth Street West
Unit B2
Oshawa, Ontario
L1J 8P7

AND TO: BIOHORIZON.COM INCORPORATED
900-400 St. Mary Ave.
Winnipeg, MB
R3C 4K5

AND TO: Lasswell Medical CO. Ltd.
405 Industrial Drive
Milton, Ontario
L9T 5B1

AND TO: Medtronic Sofamor Danek USA Inc.
c/o CT Corporation System
75 Beattie Place
Greenville, South Carolina
29601

AND TO: SpinalGraft Technologies LLC
c/o CT Corporation System
800 South Gay Street
Suite 2021
Knoxville, Tennessee
37929-9710

AND TO: Regeneration Technologies Inc.
The Prentice-Hall Corporation System Inc.
2711 Centerville Road, Suite 400
Wilmington, Delaware
19808

AND TO: Biomedical Tissue Services Ltd.
c/o Michael Mastromarino
260 Columbia Avenue Suite #1
Fort Lee, New Jersey
07024

AND TO: Michael Mastromarino
260 Columbia Avenue Suite #1
Fort Lee, New Jersey
07024

AND TO: Joseph Nicelli
29 Clifton Avenue Suite #1
Fort Lee, New Jersey
07024

CLAIM

1. The Plaintiff claims, on his own behalf and on behalf of all class members:
 - (a) an order certifying this action as a class proceeding, appointing him as the representative Plaintiff and appointing his counsel as class counsel;
 - (b) a declaration that the Defendants owed a duty of care to the Plaintiff and the class members, and that the Defendants negligently breached that duty in respect of their research, testing, manufacturing, distributing, warning and recall of certain tissue and bone products, which had been improperly obtained and screened and which were distributed in Canada by the Defendants and/or sold to corporations, including Defendant corporations, which distributed them in Canada (and which are more fully described in paragraphs 30 and 31 and hereinafter referred to as the “Recalled Tissue and Bone”), and that the Defendants are liable to the class for damages;
 - (c) an order requiring the Defendants to fund the cost of medical monitoring of all patients who received the Recalled Tissue and Bone;
 - (d) general damages in the amount of \$100 million dollars;
 - (e) special damages in the amount of \$100 million dollars, or such other amount as this Honourable Court may find appropriate;
 - (f) punitive, aggravated and exemplary damages in the amount of \$10 million dollars, or such other amount as this Honourable Court may find appropriate;
 - (g) a reference or such other directions as may be necessary to determine issues not determined at the trial of the common issues;

- (h) pre-judgment interest pursuant to the Courts of Justice Act, R.S.O. 1990, c. C43, as amended;
- (i) costs of this action on a substantial indemnity scale, plus G.S.T. ; and
- (j) such further and other relief this Honourable Court may deem just.

The Nature of the Action

2. This class action concerns the Defendants' research, testing, manufacturing, distributing, warning and recall of tissue and bone products that were improperly obtained, screened and distributed in Canada by the Defendants and/or sold to corporations, including Defendant corporations, which distributed them in Canada for transplantation into human bodies.
3. On or about October 2005, Health Canada and the U.S.A. Food and Drug Administration advised the public of a voluntary recall of the above-noted tissue and bone products (the "Recalled Tissue and Bone", which is more fully described at paragraphs 30 and 31 herein). The Recalled Tissue and Bone may not have met Health Canada donor eligibility requirements and may not have been screened for infectious diseases.
4. The Plaintiff and other class members received the Recalled Tissue and Bone during orthopaedic and dental procedures. As a result of fact that the Recalled Tissue and Bone may not have met donor eligibility requirements or been properly screened for infectious diseases, the Plaintiff and other

class members were required to undergo testing for infectious diseases, including testing for HIV, hepatitis and syphilis. Due to the dormant nature of some infectious diseases, the Plaintiff and other class members will require testing for the duration of their lives.

The Parties

5. The Plaintiff, Clarence Renaud, ("Clarence"), resides in the City of Windsor, in the province of Ontario. On April 27, 2003, Clarence was a patient at Hotel Dieu Grace Hospital in Windsor, Ontario, at which time he underwent spinal column surgery. During his surgery and unknown to him, Clarence received the Recalled Tissue and Bone (which is more fully described at paragraphs 30 and 31).
6. The Defendant, Zimmer Dental Medical Incorporated, ("Zimmer"), is an Ontario corporation with its principal place of business located in Mississauga, Ontario. Zimmer carries on business as a researcher of joint replacement solutions for knee pain and hip pain and provides spine care solutions for acute and chronic back pain. Zimmer also manufactures and distributes a range of trauma, dental implant and orthopaedic surgical products.
7. The Defendant, Mentor Medical Systems (Canada) Inc., ("Mentor"), is a Canadian corporation with its principal place of business located in Oshawa, Ontario. Mentor carries on business as a distributor of medical products for urology, ophthalmology and plastic surgery.

8. The Defendant, BIOHORIZON.COM INCORPORATED (“BIOHORIZON”), is a Canadian corporation with its principal place of business located in Winnipeg, Manitoba. BIOHORIZON carries on business as a distributor of dental equipment and supplies and also manufactures dental implants and surgical instruments.
9. The Defendant, Biogenics Inc. (“Biogenics”), is an Ontario corporation with its principal place of business located in Markham, Ontario. Biogenics carries on business as a manufacturer and distributor of instruments for cryobiology, assisted reproduction and the life sciences.
10. The Defendant, Lasswell Medical CO. Ltd. (“Lasswell”), is an Ontario Corporation with its principal place of business located in Milton, Ontario. Lasswell carries on business as a manufacturer and distributor of surgical equipment and instruments.
11. The Defendant, Medtronic of Canada Ltd. (“Medtronic Canada”), is a Canadian corporation with its principal place of business located in Toronto, Ontario. Medtronic Canada carries on business as a manufacturer of implantable and therapeutic devices for chronic diseases.
12. The Defendant, Medtronic Sofamor Danek USA, Inc. (“Medtronic USA”), is a Tennessee corporation with its principal place of business located in Memphis, Tennessee. Medtronic USA carries on business as a provider of a range of capabilities for neurological and spinal therapies.

13. The Defendant, SpinalGraft Technologies LLC (“SpinalGraft”), is a subsidiary of Medtronic USA. SpinalGraft is a Tennessee corporation with its principal place of business located in Memphis, Tennessee. SpinalGraft carries on business as a distributor of tissue, bones and organs.
14. The Defendant, Regeneration Technologies Inc. (“RTI”), is a Delaware corporation with its principal place of business located in Alachua, Florida. RTI carries on business as a processor of human tissue for allogenic grafts used in orthopaedic, oral, maxillofacial, urinary and cardiovascular surgeries.
15. The Defendant, Biomedical Tissue Services Ltd. (“BTS”), is a New Jersey corporation with its principal places of business located in Brooklyn, New York and Fort Lee, New Jersey. BTS is a human tissue recovery firm dealing with human cells, tissue and cellular and tissue based products.
16. The Defendant, Michael Mastromarino (“Mastromarino”), is an individual who resides in Fort Lee, New Jersey. Mastromarino is a former New Jersey dentist and oral surgeon who opened BTS in conjunction with the Defendant, Joseph Nicelli (“Nicelli”), for the purpose of harvesting human cells, cellular and tissue based products.
17. The Defendant, Nicelli, is an individual who resides in Staten Island, New York.
18. The Plaintiff states that the Defendants, either directly or indirectly through their partners, affiliates, agents, or servants, held themselves out to the

public as businesses engaged in the sale, promotion, marketing, harvesting, testing, procurement, sterilization, preservation, evaluation, labelling, advertising and distribution of products from human tissues and bones for medical use and implantation in the human body to hospitals, physicians, and surgery centres across Canada.

19. At all material times, the Defendants promoted and marketed their products to health care providers and the general public with assurances of safety, fitness and merchantability.

The Classes

20. This action is brought on behalf of the following classes of persons:

Class 1 Members:

“All persons in Canada, who suffered damages as a result of receiving the Recalled Tissue and Bone, specifically tissue and bone which were improperly obtained, screened, researched, tested, manufactured, distributed and/or sold by the Defendants and which are more fully described at paragraphs 30 and 31.”

Class 2 Members:

“All persons, including executors, administrators, personal representatives, spouses and relatives who, by reason of a personal relationship to a Class 1 member, have a derivative claim for damages.”

The Recalled Tissue and Bone

21. The Plaintiff states that in or around early 2000, the Defendant, Mastromarino, entered into a partnership with the Defendant, Nicelli, to open BTS for the purpose of harvesting human tissue, bone and organs from human corpses for resale to commercial human tissue, bone and organ processors and resellers. When human tissue, such as ligaments, tendons, heart valves, skin, or bone are removed from one human for preparation and transplantation into another, the tissue, bone, or organ is known as an allograft. The allograft is implanted into patients undergoing orthopaedic, dental, oral maxillofacial, urinary, and cardiovascular surgeries.
22. Shortly after opening BTS, Mastromarino and Nicelli, as well as their agents and employees, began harvesting tissue and bones from human bodies they improperly obtained from various funeral homes, and perhaps from local city morgues in cases where the bodies were unclaimed or unidentified.
23. The deceased individuals who BTS obtained from funeral homes and who were dissected by Mastromarino and/or his agents and employees never intended to be tissue donors or did not give their consent to have their tissue or bones removed with the correct authorization, and their families never authorized the use of their bodies for human tissue harvesting or later transplantation.
24. The Plaintiff states that BTS, Mastromarino, Nicelli and/or their agents or employees secretly dissected the bodies they obtained and prepared them

for burial or cremation without the knowledge of their family members. Such dissections included replacement of harvested bone and tissue with foreign objects, such as PVC piping and other objects, so that bodies would still appear normal for their pending visitations and funerals.

25. The Plaintiff further states that BTS, Mastromarino, Nicelli, and/or their agents or employees also altered the medical records, death certificates and even identities of the corpses to conceal the lifestyle and medical or disease histories of the corpses. Thus, they harvested and sold tissue or bone for implantation that came from persons who potentially suffered chronic infectious diseases such as syphilis, HIV-1, HIV-2, AIDS, or Hepatitis and who died from the diseases of cancer or heart disease.
26. Once removed, the human tissue or bones were sold by BTS to certain commercial tissue processing and allograft distribution companies, including RTI, Medtronic USA and SpinalGraft. The human tissue and bones were then sold by BTS, RTI, Medtronic USA and/or SpinalGraft to Zimmer, Biogenics, Medtronic Canada, Mentor, BIOHORIZON and Lasswell for processing and resale throughout Canada; the particulars of said transactions not being within the knowledge of the Plaintiff. In entering these business transactions, the Defendants knew or through due diligence should have known, that BTS improperly obtained and harvested the tissue and bones and as such, the Defendants both explicitly and implicitly encouraged such activities through their ongoing business relationship.

27. The Plaintiff further states that the Defendants knew of or failed to timely recognize or acknowledge the deficient procurement, testing, handling, screening, or consent of the donor and donor product, but nonetheless proceeded to permit the products to enter into the stream of commerce without taking further steps to ensure that the Recalled Tissue and Bone (more fully described at paragraphs 30 and 31) had been screened to ensure that they had not originated from persons who had died from or been infected with any of the diseases referred to in paragraphs 30 and 35 or any other infectious or other diseases.
28. On or about October 26, 2005, the U.S.A. Food and Drug Administration advised the public of a voluntary recall of human tissue for implantation of all tissue and bone product distributed by BTS.
29. On or about October 26, 2005, Health Canada issued a news release advising Canadians of the above-noted recall in the United States of America. Health Canada is a Department of the Federal Government of Canada charged with the responsibility for helping Canadians maintain and improve their health and in particular the creation and implementation of technical requirements regarding the safety of cells, tissues and organs for transplantation, as well as the safety requirements for human cells, tissues and organ transplantations. In conjunction with the news release, Health Canada sent a letter to the Canadian importers of the recalled products advising them to notify all users who received the Recalled Tissue and Bone (more fully described at paragraphs 30 and 31) and notified the chief

medical officers of Health for the provinces and territories for patient notification purposes.

30. Through its October 26, 2005 news release, Health Canada also advised that the Recalled Tissue and Bone consisted of tissues, including processed human bone, skin and tendons, that were recovered by BTS from tissue donors who may not have met Health Canada donor eligibility requirements and who may not have been properly screened for certain infectious diseases, including HIV-1 and 2 (the viruses that cause AIDS), hepatitis B virus (HBV), hepatitis C virus (HCV), human T-cell lymphotropic virus (HTLV 1 and II) and syphilis. Health Canada estimated that approximately 300 tissue products originating from BTS were imported into Canada.
31. Health Canada in its October 26, 2005 news release, further advised that BTS sold products to a number of U.S. corporations that exported tissues to Canada and that these corporations had all issued voluntary recalls for all products produced using BTS tissues and bones.
32. On or about January 17, 2006, Clarence received a letter from Patricia Somers, Vice President Patient Services and Chief Nursing Executive from Hotel Dieu Grace Hospital, advising him of the voluntary recall noted above and of the fact that he received recalled tissue products during his April 2003 surgery. He was further advised that the recalled tissue products were recovered from donors who may not have met Health Canada donor eligibility requirements and who may not have been properly screened for

- certain infectious diseases. Clarence also received a brief telephone call from Dr. Art Kidd, the Chief of staff at Hotel Dieu Grace Hospital, in which he confirmed the information set forth in the aforesaid letter from Ms. Somers.
33. Despite the fact that the Defendants were aware of the recall of the tissue products, the Plaintiff was not contacted or advised of a recall until approximately three months thereafter.
34. When the Plaintiff was eventually contacted by Hotel Dieu Grace Hospital, he was advised that he should immediately undergo testing for infectious diseases. Very shortly thereafter he was tested for HIV-1, HIV-2, Hepatitis B, Hepatitis C, Human T-cell Lymphotropic and syphilis.
35. HIV, Hepatitis B and Hepatitis C and Human T-cell Lymphotropic are potentially life threatening, incurable diseases. Syphilis can lead to sterility if left untreated. Each of the above-noted diseases carry the added stigma of being known as sexually transmitted diseases.
36. Although the Plaintiff is emotionally distraught and outraged by having the stolen and improperly processed tissue or bone in his body, the Plaintiff cannot have his allograft removed or replaced due to the inherent risk associated with further surgery.

Duty of Care

37. The Defendants' conduct fell below the reasonable standard of care expected of them under the circumstances. The Defendants owed a duty of

care to the Plaintiff and other class members to ensure that all tissue products sold by them were safe, free from diseases and reasonably fit for human implantation.

38. The Defendants placed the Recalled Tissue and Bone into the normal stream of commerce with the knowledge, intention and expectation that the products would be sold and ultimately transplanted into members of the public, including the Plaintiff. The Defendants did this without proper investigation into the origin of the products or without testing for the diseases listed in paragraphs 30 and 35 of this Statement of Claim.
39. The Plaintiff states that the Defendants, in acquiring tissue, bones and organs for making allografts are subject to their own internal procedures, based on industry standards, as well as the guidelines developed by Health Canada.
40. In or about January of 2003, Health Canada circulated a Directive entitled “Technical Requirements to Address the Safety of Cells, Tissues and Organs for Transplantation (Directive) and Safety Requirements for Human Cells, Tissues and Organs for Transplantation (Guidance Document)” to establishments and individuals involved in the handling and/or processing of human cells, tissues and organs for transplantation. The Directive described the technical requirements in respect of human cells, tissues and organs and was meant to advise the applicable establishments and individuals of the importance of adhering to standards of safety with respect to the

processing, distribution and importation of these products for transplantation.

41. The Defendants knew or ought to have known that the failure to take proper care in the distribution of the Recalled Tissue and Bone could cause serious injury, loss, and damage to members of the public, including the Plaintiff.
42. The Defendants knew or ought to have known that the standard of care applicable to their behaviour was particularly high since it was distributing tissue products intended to be implanted into humans.

Breach of Sale of Goods Act

43. The Defendants entered into contracts of sale for valuable consideration. The contracts of sale contained express and implied conditions and warranties that the products sold were reasonable for human implanting, and/or were of merchantable quality and safe and free from harmful contaminants. The Plaintiff relies on the provisions of the *Sale of Goods Act*, R.S.O. 1990, chapter S.1.
44. The Defendants products were not reasonably fit for the purpose intended.

Allegations of Negligence

45. At all material times, the Defendants negligently procured, harvested, tested, screened, researched, evaluated, preserved, supplied, marketed, distributed, labelled, advertised, sold, warned or failed to warn of the dangers associated with the Recalled Tissue and Bone.

46. The Plaintiff states that his damages were caused by the negligence of the Defendants, particulars of which negligence include, but are not limited to the following:
- a) failing to adequately screen the Recalled Tissue and Bone;
 - b) failing to adequately test the Recalled Tissue and Bone;
 - c) failing to adequately research the origin of the Recalled Tissue and Bone;
 - d) failing to adequately inspect the death certificates of the donors of the Recalled Tissue and Bone;
 - e) failing to adequately inspect the donor consents in respect of the Recalled Tissue and Bone;
 - f) failing to reject said Recalled Tissue and Bone when they knew or ought reasonably to have known that the information regarding the identities, health and cause of death of the donors thereof was inaccurate and/or incomplete;
 - g) failing to conduct periodic reviews of testing procedures;
 - h) failing to ensure compliance with donor eligibility requirements;
 - i) failing to conduct laboratory testing of tissue and blood samples from the donor for potential infectious diseases;
 - j) failing to use validated tissue preparation processes;
 - k) failing to warn of the dangers associated with the subject donor tissue; and
 - l) other allegations of negligence not presently within the knowledge of the Plaintiff.

Negligent Misrepresentations

47. Further, the Defendants made numerous negligent misrepresentations to the general public, the Plaintiff and other class members and health care

providers, leading the health care providers, among others, to believe that the Recalled Tissue and Bone were safe, sterile, and uncontaminated, without any reasonable grounds for believing the representations to be true.

48. At all material times, the Defendants' representations were made with the intent to induce the Plaintiff and other class members' health care providers and the general public to rely on them.
49. The representations made by the Defendants were false. The Recalled Tissue and Bone were not safe and had dangerous and potentially life-threatening effects and consequences.
50. At all material times, the Plaintiff and other class members were unaware of the falsity or misleading nature of the Defendants' representations and acted in reliance on the truth of the representations and were justified in so doing. Had the Plaintiff, other class members and their healthcare providers known the truth, the Plaintiff and other class members would not have accepted the Recalled Tissue and Bone into their bodies and the health care providers would not have used the Recalled Tissue and Bone.

Damages

51. As a direct result of the Defendants' acts and omissions as aforesaid, the Plaintiff and other class members have suffered or shall in the future suffer severe personal injuries, and pain and suffering, including but not limited to severe emotional distress and harm.

52. Further, the Defendants' acts and omissions constituted conduct that was negligent, intentional and caused the Plaintiff and other class member's severe emotional distress, given the nature of the harm caused and that potentially could be caused. Further and in the alternative, the Defendants' wrongful acts were committed with reckless disregard for the Plaintiff and other class members.
53. The Plaintiff has suffered nervous shock, stress and anxiety since being informed of the risk of infection and the need for ongoing medical testing. Given that some of the potential infectious diseases may lay dormant for several years, the Plaintiff and other class members will be subject to repeated testing for the duration of their lives.
54. The Plaintiff and other class members will also suffer or will already have suffered special damages, losses and expenses, including medical, hospital and other expenses related to the diagnosis, treatment and monitoring of their health status, as well as financial or economic losses, including but not limited to obligations for medical services and expenses, present and future lost wages, and other damages not now known to the Plaintiff.

Monitoring

55. As a result of the conduct of the Defendants as aforesaid, the Plaintiff has been exposed to the hazards of receiving human body parts through

transplant surgery which were, at a minimum, potentially infected with the diseases listed in paragraphs 30 and 35 of the Statement of Claim.

56. The Plaintiff's exposure to infection results from receiving potentially infectious transplant products during his surgery and was greater than normal since the transplanted parts were not tested for infectious diseases.
57. As a direct and proximate result of receiving the Recalled Tissue and Bone, the Plaintiff has a significant increased risk of contracting a serious latent disease.
58. Monitoring procedures exist that can provide early detection of diseases. The prescribed regime is different from that normally recommended in the absence of such exposure. The regime is reasonably necessary according to contemporary scientific principles.
59. The Plaintiff claims the benefit of a monitoring program, funded by the Defendants but administered at arm's length from the Defendants.

Punitive, Aggravated and Exemplary Damages

60. The Defendants misled both the medical community and the public, including the Plaintiff, by making false representations about the safety of the tissue products and acting in an intentional manner with malice and wilful disregard for the safety of others.
61. At all material times, the Defendants knew or should have known that the

duties and responsibilities of a responsible manufacturer of improperly obtained and screened tissue products included the immediate notification of the Plaintiff and the other class members, and their health care providers, of the dangers posed by the implantation of the Recalled Tissue and Bone, yet they took no steps to contact either the purchasers of their products or the Plaintiff or other class members.

62. The Plaintiff states that the Defendants, in their failure to research, test and warn the Plaintiff and other class members of the improperly obtained and screened products, exposed the Plaintiff and other class members to greatly increased risks of injury or death, preferring profit to patient safety. In so doing, the Defendants acted in a callous and high handed manner and their conduct merits a significant award of punitive, aggravated and exemplary damages.

Damages of the Provincial Health Insurers

63. As a result of the use of improperly obtained and screened donor tissue, many class members will have to undergo continual testing for latent diseases. The provincial health insurers will be required to pay for additional medical treatment and monitoring costs.
64. The provincial health insurers have paid for the past insured services and will be required to pay for extensive and costly future insured services.

Relevant Statutes, Regulations and Guidelines

65. The Plaintiff pleads and relies upon the following:

- a) *Sale of Goods Act*, R.S.O. 1990, c.S.1;
- b) *The Class Proceedings Act*, S.O. 1992, c.S.1;
- c) *The Negligence Act*, R.S.O. 1990, c.N.1;
- d) *Health Insurance Act*, R.S.O. 1990 c. H.6;
- e) *The Food and Drugs Act*, R.S.C. 1985, c. F-27, as amended and regulations made pursuant thereto;
- f) *Family Law Act*, R.S.O. 1990, c.F.3; and
- g) *The Trustee Act*, R.S.O. 1990, C.T.23 as amended.

REAL AND SUBSTANTIAL CONNECTION WITH ONTARIO

66. The Plaintiff pleads that this action has a real and substantial connection with Ontario because, among other things:

- a) the Defendants carry on business in Ontario and elsewhere in Canada and/or sold or distributed the Recalled Tissue and Bone to corporations, including Defendant corporations, which carry on business in Ontario and elsewhere in Canada;
- b) the Defendants market their products in Ontario and/or elsewhere in Canada;
- c) the Plaintiff's damages were sustained in Ontario; and
- d) a substantial portion of members of the putative class reside in Ontario.

Service of this Statement of Claim Outside of Ontario

67. This Statement of Claim may be served without court order outside Ontario, Canada, in that the proceeding against the Defendants consists of claims:

- a) in respect of a contract made in Ontario (Rule 17.02 (f));
- b) in respect of a tort committed in Ontario (Rule 17.02(g));
- c) in respect of damage sustained in Ontario arising from a tort or breach of contract, wherever committed (Rule 17.02 (h));
- d) against a person outside Ontario who is a necessary or proper party to this proceeding properly brought against another person served in Ontario (Rule 17.02 (o)); and
- e) against a person carrying on business in Ontario (Rule 17.02 (p)).

Place of Trial

68. The Plaintiff proposes that this action be tried in the City of Windsor, in the County of Essex and Province of Ontario.

Date of Issue:

GREG MONFORTON AND PARTNERS
GREG MONFORTON LSUC#--021433B
NEERU K. SCHIPPEL LSUC#--50599K
13th Floor—100 Ouellette Avenue
Windsor, Ontario
N9A 6T3
Tel: (519) 258-6490
Fax: (519) 258-4104

Solicitors for the Plaintiff