

**ONTARIO  
SUPERIOR COURT OF JUSTICE**

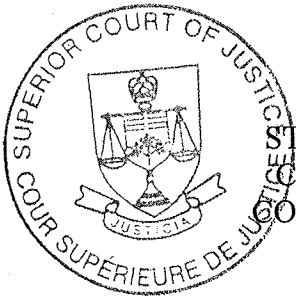
THE HONOURABLE ) MONDAY, THE  
JUSTICE BELOBABA ) 6<sup>TH</sup> DAY OF JANUARY, 2020

**BETWEEN:**

**ROSEMARY RITLOP and DONILDA LACKNER**

**Plaintiffs**

**- and -**



**STRYKER CANADA LP, STRYKER CANADA CORP., STRYKER  
CANADIAN MANAGEMENT INC., HOWMEDICA OSTEONICS  
CORPORATION c.o.b. as STRYKER ORTHOPEDICS and STRYKER  
CORPORATION**

**Defendants**

*Proceeding under the Class Proceedings Act, 1992*

**ORDER**

**THIS MOTION**, made by the representative Plaintiffs for approval of the settlement of this action pursuant to s. 29 of the *Class Proceedings Act, 1992*, in accordance with the terms of the Settlement Agreement was heard this day in Toronto.

**UPON READING** the Representative Plaintiffs' motion record, and upon hearing the submissions of counsel for the representative Plaintiff and counsel for the Defendants, fair and adequate notice of the within hearing having been provided to Class Members;

**THIS COURT ORDERS AND DECLARES** that:

1. The definitions set out in the Settlement Agreement, which is attached hereto as Schedule "A", apply to and are incorporated into this Order.

2. The notice to Class Members of the within hearing, as set out in the report of Epiq Class Actions Services Canada Inc. attached as Exhibit "A" to the Affidavit of C. Baracao sworn January 3rd, 2020, was fair and reasonable, notwithstanding any lack of compliance by the Hospitals with the August 23rd, 2019 Order.
3. The settlement of this action, as set out in the Settlement Agreement, is fair, reasonable, and in the best interests of the Class Members, and is hereby approved pursuant to s. 29 of the Class Proceedings Act, 1992 and shall be implemented in accordance with its terms.
4. The Settlement Agreement and this Order are binding upon the Representative Plaintiffs and each Class Member, whether or not such person receives or claims compensation, including persons who are minor or are mentally incapable.
5. The Defendants shall pay the amounts required under the Settlement Agreement, subject to the Right of Termination set out in Section 8 of the Settlement Agreement.
6. The form and content of the Notice of Approval of Settlement shall be substantially in the form which appears at Schedule E to the Settlement Agreement.
7. Class Members shall be given notice of this order in accordance with the plan attached as Schedule F to the Settlement Agreement. The notice shall be available in both English and French.
8. The notification plan described in Schedule F to the Settlement Agreement satisfies the requirements of s. 17 of the Class Proceedings Act.
9. Epiq Class Action Services Canada Inc. is hereby appointed as Claims Administrator.
10. Upon the Effective Date, the Released Persons are forever and absolutely released by the Releasing Persons from the Released Claims including, but not limited to all claims, actions, causes of action, suits, debts, duties, accounts, bonds, covenants, contracts, and demands whatsoever that were asserted, or could have been asserted, and that are the subject of this Settlement Agreement. The Releasing Persons are barred from taking or continuing any proceedings arising out of or relating to the Released Claims against any other person, corporation, or entity (including, without limitation, any health care professionals, health care

providers, or health care facilities) that might claim damages and/or contribution and indemnity and/or other relief under the provisions of the Negligence Act or other comparable provincial legislation and any amendments thereto, the common law, Quebec civil law, or any other statute, for any relief whatsoever, including relief of a monetary, declaratory, or injunctive nature, from one or more of the Released Persons.

11. The Releasing Persons shall not now or hereafter institute, continue, maintain, or assert, either directly or indirectly, whether in Canada or elsewhere, on their own behalf or on behalf of, or as part of, any class or any other person, any action, suit, cause of action, claim, or demand relating to the Released Claims against any Released Persons. No Class Members shall recover, directly, indirectly, or derivatively any sum from Defendants or Released Persons other than the sum authorized under the Settlement Agreement in connection with the Affected Product.

12. Neither the Settlement Agreement (including all terms thereof) nor performance under the terms of the Settlement Agreement by the Defendants is, or shall be, construed as any admission by the Defendants, including but not limited as to: (1) the validity of any claim, theory, or fact; (2) any liability, fault, or responsibility; or (3) the existence, cause, or extent of any damages or losses alleged or suffered by the Representative Plaintiff or any Class Member.

13. This Court shall have continuing jurisdiction over the implementation and enforcement of the Settlement Agreement.

14. This action is hereby dismissed without costs and with prejudice.



Justice Belobaba

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ON / BOOK NO:  
LE / DANS LE REGISTRE NO..

JAN 07 2020

PER / PAR:



SCHEDULE "A"

Court File No. CV-14-504302-00CP

**ONTARIO  
SUPERIOR COURT OF JUSTICE**

BETWEEN:

**ROSEMARY RITLOP and DONILDA LACKNER**

(the "Plaintiffs")

- and -

**STRYKER CANADA LP, STRYKER CANADA CORP.,  
STRYKER CANADIAN MANAGEMENT INC., HOWMEDICA  
OSTEONICS CORPORATION c.o.b. as STRYKER ORTHOPEDICS,  
and STRYKER CORPORATION**

(the "Defendants", together with the Plaintiffs, the "Parties")

Proceeding under the *Class Proceedings Act, 1992*

**CANADIAN REJUVENATE MODULAR CLASS SETTLEMENT**

**RECITALS**

- A. WHEREAS the Plaintiffs commenced Action No. CV-14-504302-00CP in the Superior Court of Justice, Ontario alleging that the Defendants marketed a defective hip implant known as the Rejuvenate Modular-Neck Hip Stem (the "Affected Product") and seeking a class of persons resident in Canada (the "Ontario Proceeding");
- B. WHEREAS Stryker Canada LP, based in Ontario, sold and distributed the Affected Product to Canadian Hospitals;
- C. WHEREAS by Order dated December 8, 2015, the Honourable Justice Belobaba certified the Ontario Proceedings as a class action on behalf of:
- (a) All persons who were implanted in Canada with the Stryker Rejuvenate Modular Hip System and were resident in Canada at the time of implant; and
  - (b) All other persons, who by reason of his or her relationship to one or more of the above, have standing to sue pursuant to Section 61 (1) of the *Family Law Act, R.S.O. 1990. C. F3* or the equivalent legislation in other provinces.

- D. WHEREAS Rosemary Ritlop and Donilda Lackner (the "Plaintiffs") were appointed as representative plaintiffs in the Ontario Proceeding;
- E. WHEREAS the Defendants deny liability in respect of the claims alleged in the Ontario Proceeding, and believe that they have good and reasonable defences in respect of the merits in the Ontario Proceeding;
- F. WHEREAS the Defendants assert that they would actively pursue these defences in respect of the merits at trial if the Plaintiffs continued the Ontario Proceeding against them;
- G. WHEREAS the Plaintiffs have agreed to accept this Settlement, in part, because of the monetary payments to be provided by the Defendants under the terms of this Settlement Agreement, as well as the attendant risk of litigation in light of the potential defences that may be asserted by the Defendants;
- H. WHEREAS the Defendants are entering into this Settlement Agreement in order to achieve a final and nation-wide resolution of all claims asserted in respect of the Affected Product or that could have been asserted against them by Plaintiffs, and the Class Members in the Ontario Proceeding or otherwise, and to avoid further expense, inconvenience, and the distraction of burdensome and protracted litigation;
- I. WHEREAS counsel for the Defendants and counsel for the Plaintiffs have engaged in extensive arm's-length settlement discussions and negotiations in respect of this Settlement Agreement;
- J. WHEREAS as a result of these settlement discussions and negotiations, the Defendants and the Plaintiffs have entered into this Settlement Agreement, which embodies all of the terms and conditions of the Settlement between the Defendants, the Plaintiffs, and the Health Insurers, subject to the approval of the Court;
- K. WHEREAS the Parties therefore wish to, and hereby do, finally resolve, without admission of liability, the Ontario Proceeding against the Defendants;
- L. WHEREAS the Defendants do not admit through execution of this Settlement Agreement any of the conduct alleged in the Ontario Proceeding or any other proceedings or any liability to Plaintiffs or to anyone;
- M. WHEREAS the Plaintiffs, Class Counsel and the Defendants agree that neither this Settlement Agreement nor any statement made in the negotiation thereof shall be deemed or construed to be an admission by or evidence against the Defendants or evidence of the truth of the Plaintiffs', or anyone else's, allegations against the Defendants;
- N. WHEREAS the Plaintiffs and their counsel have reviewed and fully understand the terms of this Settlement Agreement; and based on their analyses of the facts and law applicable to the Plaintiffs, and having regard to the burdens and expense in prosecuting the Ontario Proceeding, including the risks and uncertainties associated with trials and appeals, the

Plaintiffs and their counsel have concluded that this Settlement Agreement is fair, reasonable, and in the best interests of the Plaintiffs and the Class they represent; and

- O. WHEREAS for the purposes of settlement only and contingent on orders by the Court as provided for in this Settlement Agreement, the Plaintiffs have consented to a dismissal of the Ontario Proceeding against the Released Persons, as that term is defined in Section 1 below, and the release of all Released Claims, as that term is defined in Section 1 below, that have been or could have been asserted against any Released Persons.

NOW THEREFORE, in consideration of the covenants, agreements, and releases set forth herein and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, it is agreed by the Parties that the Ontario Proceeding be settled and dismissed on the merits with prejudice to the Releasing Persons, on the following terms and conditions:

### **Section 1 Definitions**

- 1.1 **General.** As used in this Settlement Agreement, and in addition to the definitions set forth in the introduction, preamble, and recitals above, capitalized terms shall have the following definitions and meanings or such definitions and meanings as are accorded to them elsewhere in this Agreement. Terms used in the singular shall be deemed to include the plural and vice versa.
- 1.2 **Terms.**
- 1.2.1 **"Account"** means an interest-bearing trust account under the control of the Claims Administrator at a Schedule 1 Canadian chartered bank. Any interest accrued will be utilized first to pay taxes and then to defray the Notice and Administration Costs.
- 1.2.2 **"Affected Product"** means the Rejuvenate Modular-Neck Hip Stem (also referred to as the "Rejuvenate Modular Hip System" or the "Rejuvenate Modular") and any and all Component and Ancillary Parts.
- 1.2.3 **"Allegations"** means any and all assertions of fact or law, causes of action, injuries and damages that were pleaded, or which could have been plead, in the Statement of Claim filed in Action No. CV-14-504302-00CP in the Superior Court of Justice, Ontario.
- 1.2.4 **"Approval Hearings"** means the hearings on the motions before the Court for the approval of the Settlement Agreement and notice approvals.
- 1.2.5 **"Approval Order(s)"** means the order(s) made by the Court in this Proceeding approving this Settlement Agreement, and the notices required with respect to the settlement, substantially in the form attached as Schedules B through C hereto.

- 1.2.6 “Approved Claim” means an Eligible Claim submitted by an Eligible Claimant and deemed qualified by the Claims Administrator or the Reconsideration Officer under the terms of this Settlement Agreement.
- 1.2.7 “Approved Claimant” means a member of the Class (including any Principal Caregiver family member) who is deemed qualified by the Claims Administrator or the Reconsideration Officer to receive payment under the terms of this Settlement Agreement.
- 1.2.8 “Base Award” means the amount available to Approved Claimants as part of this Settlement before the application of any applicable reductions, limitations, or qualifying Enhancements.
- 1.2.9 “Bilateral Revision” means a Class Member who had an Affected Product implanted into both his/her left and right hips and has undergone Revision Surgery(ies) to remove both Affected Products.
- 1.2.10 “Canadian Patient” means persons who underwent an Index Surgery in Canada and were resident in Canada at the time of the Index Surgery. This agreement specifically excludes foreign residents or patients who had an Index Surgery in foreign countries. This agreement does not cover Rejuvenate Modular products implanted outside of Canada.
- 1.2.11 “Canadian Rejuvenate Modular Settlement Program” or “Settlement Program” means the claims process and settlement awards available for qualifying Eligible Claimants who are Class Members, which is established by the terms of this Settlement Agreement, subject to Final Approval and the Effective Date.
- 1.2.12 “Claim Form” means the form and declaration attached as Schedule A.
- 1.2.13 “Claims Administrator” means Epiq Class Action Services Canada Inc., the entity selected by the agreement of Class Counsel and the Defendants to administer the Settlement Program, including but not limited to administering the Settlement Program to receive, review, and evaluate claims; render settlement awards or deny claims; facilitate the appeal process; and process the payment of final settlement awards.
- 1.2.14 “Claims Amount” means the amounts to which an Approved Claimant is entitled following the application of all reductions according to the terms of this Settlement Agreement.
- 1.2.15 “Claims Period/Current Deadline” means the period commencing with the date of the Claims Administrator’s first mailing of the Notice of Settlement Approval and continuing until 210 days thereafter. The Claims Period/Current Deadline is applicable to Class Members who are Eligible Claimants making a claim about a Qualified Revision Surgery that occurred before the Effective Date, and all claims related to a Medically Precluded Claimant.

- 1.2.16 "Claims Period/Future Deadline" means the period commencing with the first publication of the Notice of Settlement Approval and continuing until 90 days after the Qualified Revision Surgery or sixty (60) days after the Last Eligible Date, whichever date is earlier. The Claims Period/Future Deadline is applicable to Class Members who are Eligible Claimants making a claim about a Qualified Revision Surgery that occurs on or after the Effective Date, but within ten (10) years of the Index Surgery, subject to the Discretionary Extension.
- 1.2.17 "Class Counsel" means Koskie Minsky LLP, Stevenson Whelton LLP, and Klein Lawyers.
- 1.2.18 "Class Counsel Fees" means all Fees approved by the Court as payable pursuant to Section 9 hereof.
- 1.2.19 "Class or Class Members" means:
- 1.2.19.1 All persons who were implanted in Canada with the Stryker Rejuvenate Modular Hip System and were resident in Canada at the time of implant; and
  - 1.2.19.2 All other persons who, by reason of his or her relationship to one of more of the above, have standing to sue pursuant to Section 61(1) of the Family Law Act, R.S.O. 1990, c. F3 or the equivalent legislation in other provinces or territories.
  - 1.2.19.3 For the avoidance of doubt, this definition excludes all Class Members who validly opted out of the Ontario Proceeding in accordance with the certification order dated December 8, 2015, including any related derivative or subrogated claims ("Opt-Out Claimants"); however, an Opt-Out Claimant who has not otherwise resolved his/her claims against Defendants related to the Affected Product may revoke his/her prior opt-out and become a Class Member by timely filing a Claim Form under this Settlement Agreement.
- 1.2.20 "Component and Ancillary Parts" means each and every component or ancillary part implanted contemporaneously with and/or intended to function as part of the prosthetic construct that includes the Affected Product.
- 1.2.21 "Contemporaneous Medical/Hospital Records" means medical/hospital records created contemporaneous with a diagnosis of a condition or complication and/or the occurrence of a surgery or other treatment for which a claim is being made.
- 1.2.22 "Costs of the Notice Program" means all third-party costs associated with the publication and distribution of the Notice of Settlement Approval Hearing and the Notice of Settlement Approval.
- 1.2.23 "Court" means the Ontario Superior Court of Justice handling the Ontario Proceeding.



- 1.2.24 “Defendants” mean Stryker Canada LP, Stryker Canada Corp., Stryker Canadian Management, Inc., Howmedica Osteonics Corp., and Stryker Corporation.
- 1.2.25 “Defendants’ Counsel” means Blake, Cassels & Graydon LLP.
- 1.2.26 “Derivative Claimant(s)” means all residents of Canada asserting the right to sue the Defendants independently or derivatively by reason of their familial relationship to a Class Member.
- 1.2.27 “Disbursements” means funds paid out by Class Counsel for expenses in connection with the Ontario Proceeding and does not include Class Counsel Fees.
- 1.2.28 “Discretionary Extension” means the discretionary extension of the Claims Period/Future Deadline by the Parties for an individual Class Member who will miss the ten-year post-Index Surgery cutoff solely due to a hospital scheduling issue. In order to be considered for a discretionary extension, an individual Class Member must provide the Parties with a supporting written declaration by his/her treating orthopaedic surgeon attesting to the reasons for the hospital scheduling issue. Failing agreement by the Parties to grant the discretionary extension, upon application to the Court, the Court may grant such an extension having regard to the written declaration by his/her treating orthopaedic surgeon and the submissions of the Parties.
- 1.2.29 “Effective Date” means the latest date on which any of the Final Orders take effect without the possibility of further appeal.
- 1.2.30 “Eligible Claimant” means a Class Member who (a) was a Canadian Patient, (b) underwent an Index Surgery, (c) underwent a Qualified Revision Surgery or is a Medically Precluded Claimant (as defined below); and (d) the Qualified Revision Surgery occurred within ten (10) years of the Index Surgery, subject to the Discretionary Extension. Eligible Claimants include the duly appointed estate or personal representatives of Eligible Claimants who had a Qualified Revision Surgery, but who are now deceased or otherwise incompetent to act on their own behalf. For clarity, Class Members who had an Index Surgery, but remain Unrevised (as defined below), and who are not Medically Precluded Claimants, are not Eligible Claimants. The Defendants, in their sole and absolute discretion, may irrevocably waive one or more criteria referenced above and deem a Class Member to be an Eligible Claimant by so informing the Claims Administrator in writing.
- 1.2.31 “Eligible Claims” means claims meeting the eligibility criteria set out in Section 4.
- 1.2.32 “Enhancement” means the specific benefit, including Income Loss, that may be available to Approved Claimants identified in Schedule H.
- 1.2.33 “Excluded Infection-Related Revision Surgery” means a surgery to remove both the femoral stem and neck component of the Affected Product that is necessitated by “Infection”. If the Contemporaneous Medical Records (e.g. admission history and physical, operative report, discharge summary or pathology report) from a Revision

Surgery taking place at least 181 days after an Index Surgery states that the cause of the Revision Surgery was an Infection, and the Contemporaneous Medical/Hospital Records show either (i) a sinus tract communicating with the affected prosthetic joint, or (ii) a pathogen isolated by culture from at least two (2) separate tissue or fluid samples obtained from the affected prosthetic joint prior to or during the Revision Surgery hospitalization (where at least one of the samples is obtained prior to or during the Revision Surgery).

If an Infection is deemed to have occurred (as set forth above) and an Infection is identified in the Contemporaneous Medical/Hospital Records (e.g. admission history and physical, operative report, or discharge summary) as the cause for revision, then the revision is not a Qualified Revision Surgery and the claimant shall be deemed unable to participate unless the Contemporaneous Medical/Hospital Records show the claimant, more likely than not, would have required a Qualified Revision Surgery regardless of the Infection.

- 1.2.34 "Excluded Trauma-Related Revision Surgery" means a surgery to remove both the femoral stem and neck component of the Affected Product that is caused by "Trauma." For purposes of this provision, the term "Trauma" is defined as a change in the alignment or fixation of the Affected Product caused by the application of an external force in a sudden or unexpected manner. Trauma affecting an Affected Product will be deemed to have occurred if a fracture or change in the position of the Affected Product, or in its alignment or fixation, is verified by radiological studies, or such change is described in Contemporaneous Medical/Hospital Records by the treating physician who attributes the cause for revision to be due to that traumatic event.

If Trauma is deemed to have occurred (as set forth above) and Trauma is identified in the Contemporaneous Medical Records (e.g. admission history and physical, operative report, or discharge summary) as the cause for revision, then the Revision Surgery is not a Qualified Revision Surgery and the claimant shall be deemed unable to participate unless the Contemporaneous Medical/Hospital Records show, more likely than not, the claimant would have required a Qualified Revision Surgery regardless of the Trauma.

- 1.2.35 "Execution Date" means the last date that the Settlement Agreement has been signed by all of the Parties.
- 1.2.36 "Final Approval Date" means the later of (a) 31 days after the Court issues an Approval Order, or (b) the disposition of any and all appeals from the Approval Order.
- 1.2.37 "Final Order" means the final order entered by the Court in respect of the approval of this Settlement Agreement once the time to appeal such orders has expired without any appeal being taken or, if an appeal from a final order is taken, once there has been affirmation of the approval of this Settlement Agreement upon a final disposition of all appeals.

- 1.2.38 "Fonds" means the *Fonds d'aide aux actions collectives*.
- 1.2.39 "Health Insurers" means all of the Canadian Provincial and Territorial Ministries of Health or governmental bodies that provide publicly funded plans of healthcare in Canada.
- 1.2.40 "Health Insurer Claims" means the entitlement of the Health Insurers to any subrogated or direct claims arising from the provision of health care services to Class Members in relation to the Allegations and pursuant to legislation that permits the recovery of healthcare costs or medical expenses from third parties, for example the British Columbia Health Care Costs Recovery Act, or similar legislation.
- 1.2.41 "Income Loss" means an amount lost in excess of twenty percent (20%) of the aggregate income for the two years preceding the Index Surgery of an Approved Claimant, up to a maximum of \$10,000 (CAD), where the loss was solely due to the Approved Claimant's Qualified Revision Surgery. Any resulting Enhancement is subject to the aggregate cap of \$65,000 (CAD) for Unilateral Claimants and \$80,000 (CAD) for Bilateral Revision Claimants for all Enhancements as set forth in Schedule H. This Enhancement is intended to provide an award to an Approved Claimant who can demonstrate an actual economic loss in connection with the Qualified Revision Surgery and specifically excludes those who were not employed and/or were retired at the time of the Qualified Revision Surgery. The calculation of Income Loss is not to include any deduction for disability payments received.
- 1.2.42 "Index Surgery" means the surgical implantation of the Affected Product in a surgery on that hip occurring in Canada.
- 1.2.43 "Index Surgery Date" means the day on which the Index Surgery occurred.
- 1.2.44 "Last Eligible Date" means July 31, 2022.
- 1.2.45 "Medically Precluded Claimant" means a claimant for whom as of the Execution Date, a Revision Surgery has been indicated for the reasons related to the underlying Voluntary Recall (see Schedule J) but is unable to undergo a Revision Surgery due to the existence of a documented medical condition. The need, and reason, for the Revision Surgery and the determination of an inability to undergo the Revision Surgery due to the existence of a documented medical condition must be established by the claimant's medical records made at the time of the respective determinations. For the avoidance of doubt, age is not a medical condition.
- 1.2.46 "Notice and Administration Costs" means all fees, costs, PST, GST and HST taxes, and any other amounts incurred for the approval, implementation, and administration of this Settlement Agreement up to a maximum of \$500,000 (CAD), including the Costs of the Notice Program, the costs of translation of the Notices, and the fees and expenses of the Claims Administrator and the Reconsideration Officer, but excluding Class Counsel Fees and Disbursements and the costs to complete and file a claim under this Settlement.

- 1.2.47 “Notice of Settlement Approval” means the form of notice, agreed to by the Class Counsel and the Defendants, as set forth in Schedule E, or such other form as may be approved by the Court, with agreement of the Parties, that informs the Class of the approval of this Settlement Agreement.
- 1.2.48 “Notice of Settlement Approval Hearing” means the form of notice agreed to by Class Counsel and the Defendants, as set forth in the attachment to Schedule D, or such other form as may be approved by the Court, with agreement of the Parties, that informs the Class Members of the date and location of an Approval Hearing, the principal elements of this Settlement Agreement, and the process by which Class Members may object to the Settlement.
- 1.2.49 “Notices” means (i) the Notice of Settlement Approval Hearing and (ii) the Notice of Settlement Approval.
- 1.2.50 “Parties” means the parties to this Settlement Agreement, including Plaintiffs, Class Counsel and the Defendants.
- 1.2.51 “Plaintiffs” means the named class representatives.
- 1.2.52 “Principal Caregiver” means a family member who provided care for a Class Member who underwent a Qualified Revision Surgery.
- 1.2.53 “Qualified Revision Surgery” means the surgery to remove an Affected Product from a Qualified Revision Surgery Patient.
- 1.2.54 “Qualified Revision Surgery Patient” means:
- 1.2.54.1 **For Claimants Revised as of September 25, 2018:** A claimant who had a Revision Surgery other than a surgery: (a) taking place within 181 days after the implant surgery; or (b) is an Excluded Infection-Related or Trauma-Related Revision Surgery, unless medical records show that the claimant would likely have required such a revision regardless of the Infection or Trauma.
- 1.2.54.2 **For Claimants Revised after September 25, 2018:** A claimant who had a Revision Surgery that (i) occurs at least 181 days after the Index Surgery but during the applicable Claim Period; (ii) is not an Excluded Infection-Related or Trauma-Related Revision Surgery, unless medical records show that the claimant would likely have required such Revision Surgery regardless of the Infection or Trauma; and (iii) involves one (1) or more of the following: (a) an elevated cobalt level, (b) an abnormal diagnostic scan associated with the tissue around the femoral implant related to the reasons underlying the Voluntary Recall, or (c) intra-operative or pathologic confirmation of ALTR, ALVAL or tissue damage related to the reasons underlying the Voluntary Recall.

1.2.55 "Reconsideration Officer" means the independent person to be employed by the Claims Administrator, or the independent person to be appointed by the Court at its discretion, to oversee the settlement administration process and make final and non-appealable decisions with respect to the adjudication of any claim decisions of the Claims Administrator that are subject to appeal pursuant to the claim processing provisions of this Settlement Agreement.

1.2.56 "Released Claims" means any and all claims, including assigned claims, of the Releasing Persons whether known or unknown, asserted or unasserted, regardless of the legal theory, existing now or arising in the future, relating to or arising out of the Affected Product(s) or its design, development, manufacture, formulation, testing, distribution, marketing, labeling, regulatory submissions, advertising, prescription, purchase, sale, implantation, use, removal, or revision and include, without limitation, all claims for damages or remedies of whatever kind or character, known or unknown, that are now recognized by law or that may be created or recognized in the future by statute, regulation, judicial decision, administrative adjudication, or in any other manner for:

- 1.2.56.1 personal injury and/or bodily injury, damage, death, fear of disease or injury, mental or physical pain or suffering, emotional or mental harm, or loss of enjoyment of life;
- 1.2.56.2 loss of wages, income, earnings or earning capacity, medical expenses, doctor, hospital surgical, nursing and drug bills as well as all direct claims for cost recovery;
- 1.2.56.3 loss of guidance, care, support, services, consortium, companionship, society or affection, or damage to familial relations, including without limitation, all claims by persons who by reason of his or her relationship to one or more Class Members having standing to sue pursuant to Section 61(1) *Family Law Act*, R.S.O. 1990 c. F. 3 or the equivalent legislation in other provinces;
- 1.2.56.4 wrongful death and survival actions;
- 1.2.56.5 medical screening or monitoring, injunctive, declaratory or equitable relief;
- 1.2.56.6 consumer fraud, refunds, restitution, unfair business practices, deceptive trade practices, unjust enrichment, waiver of tort, lack of efficacy, money had and received and other similar claims;
- 1.2.56.7 compensatory damages, punitive or exemplary damages, statutory and other multiple damages or penalties of any kind;
- 1.2.56.8 economic or business losses, diminished value or lost benefit-of-the-bargain;

1.2.56.9 lawyer's fees, costs, court, litigation or other expenses; and/or

1.2.56.10 prejudgment or post-judgment interest.

1.2.56.11 As it relates to the Health Insurers, any Health Insurer Claims which a Health Insurer ever had, now have, or hereafter can, shall, or may have arising out of or in any way connected with injuries allegedly suffered by the Class Members and relating directly or indirectly to the Allegations and pursuant to legislation that permits the recovery of healthcare costs or medical expenses from third parties, for example, the British Columbia Health Care Costs Recovery Act, or similar legislation.

1.2.56.12 For the avoidance of doubt, Released Claims does not include the claims of any Opt-Out Claimant, and any related derivative or subrogated claims (including the related claims of Health Insurers), who does not revoke his/her opt-out as set forth in Section 1.2.19.3.

1.2.57 "Released Persons" means:

1.2.57.1 The Defendants and each of their past, present and future direct or indirect parent companies, subsidiaries, divisions, affiliated or related companies, joint ventures, joint venturers, inventors, designers, patent holders, manufacturers, distributors, retailers (including, without limitation, wholesale distributors, private label distributors, retail distributors, pharmacies and pharmacists), physicians, surgeons, hospitals, or other prescribers, clinical researchers, contractors and consultants, and each of their present and former officers, directors, employees, stockholders, partners, owners, insurers, attorneys, representatives and agents, Crawford & Company, Inc. (only in respect of the Broadspire Program), and each of their predecessors, successors and assigns;

1.2.57.2 any and all manufacturers, suppliers (including suppliers of materials, machines or equipment used in the manufacture of the Affected Product), purchasers, licensors, licensees and sponsors of the Affected Product or any raw materials used in the Affected Product distributed or marketed by any of the persons in subparagraph above; each of their parent companies, subsidiaries, divisions, affiliates, joint ventures, joint venturers, distributors, retailers (including, without limitation, wholesale distributors, private label distributors, retail distributors, pharmacies and pharmacists), clinical researchers, contractors and consultants; each of their present and former officers, directors, employees, stockholders, partners, owners, insurers, attorneys, representatives, and agents; and each of their predecessors, successors and assigns; and

1.2.57.3 any other person or entity involved in the development, design, manufacture, formulation, testing, distribution, marketing, labeling, regulatory submissions, advertising or sale of the Affected Product; each

of their present and former officers, directors, employees, stockholders, partners, owners, insurers, attorneys, representatives and agents; and each of their predecessors, successors and assigns.

- 1.2.58 “Releasing Persons” means all Class Members, including (i) all Derivative Claimants, and (ii) the Health Insurers, and each of their respective successors, heirs, estates, administrators, trustees, assigns, and their affiliated predecessor, successor, and related companies or entities (as applicable).
- 1.2.59 “Revision Surgery” means the explantation of both the femoral stem and neck of the Affected Product that was originally implanted during an Index Surgery.
- 1.2.60 “Settlement Agreement” or “Settlement” means this Agreement, including the Recitals and Schedules hereto.
- 1.2.61 “Settlement Amount” means the aggregate amount payable by the Defendants pursuant to Section 4.
- 1.2.62 “Settlement Award” means the individual award given to an Approved Claimant pursuant to this Settlement Agreement.
- 1.2.63 “Termination Right” means the right of Defendants to terminate this Settlement Agreement at its option in the event one or more of the circumstances set forth in this Settlement Agreement occurs or fails to occur.
- 1.2.64 “Unilateral Revision” means a single Revision Surgery on one hip of a Class Member.
- 1.2.65 “Unrevised” means any Class Member who has not undergone a Revision Surgery by the Last Eligible Date.
- 1.2.66 “Voluntary Recall” means the June 28, 2012 voluntary recall of the Affected Product.

## Section 2 Calculation of Deadlines and Condition Precedent

- 2.1 If any deadline identified in the Settlement Agreement falls on a weekend or Canadian national holiday, the deadline shall occur on the following weekday that is not a Canadian national holiday.
- 2.2 Subject to Section 8 below, this Settlement Agreement shall be null and void and of no force or effect unless the Court approves this Settlement Agreement, and the orders so made have become Final Orders and the Effective Date has occurred.

**Section 3**  
**Settlement Approval**

- 3.1 **Best Efforts.** The Parties shall use their best efforts to effect this Settlement and to secure the prompt, complete and final dismissal with prejudice of the Ontario Proceedings against the Defendants.
- 3.2 **Motion Approving Notice of Settlement Approval Hearing.** At times mutually agreed to by the Parties after the Settlement Agreement is executed, Class Counsel shall bring a motion before the Court for an order approving a Notice of Settlement Approval Hearing and proposed dissemination plan in respect of the Notice of Settlement Approval Hearing. The form of order on notice of the hearing, the proposed Notice of Settlement Approval Hearing, and the Plan for the Dissemination shall substantially accord with Schedules B, D and F, respectively.
- 3.3 **Motion for Approval of Settlement.** Following Court approval of the Plan for the Dissemination of the Notice of Settlement Approval Hearing, Class Counsel shall file a motion in the Court for an order approving this Settlement Agreement. The form of order approving the Settlement, the proposed Notice of Settlement Approval and the Plan for the Dissemination shall substantially accord with Schedules C, E and F, respectively.
- 3.4 **Effect of Court's Approval Order.** Subject to the Court's approval, the order approving this Settlement Agreement shall:
- 3.4.1 Approve this Agreement and order the Parties and all Class Members who have not validly opted out to comply with it;
  - 3.4.2 Declare that this Agreement is reasonable, fair, adequate and in the best interest of the Class;
  - 3.4.3 Confirm the appointment of the Claims Administrator;
  - 3.4.4 Enter such other orders as are needed to effectuate the terms of this Settlement Agreement; and
  - 3.4.5 Enjoin all Class Members who have not validly opted out from asserting and/or continuing to prosecute claims against Defendants or any other Released Person, as well as any Released Claim that such Class Member has, had or may have in the future.
- 3.5 **Publication of the Notice of Settlement Approval Hearing.** Before the Settlement Agreement has been approved by the Court, Class Counsel shall disseminate the Notice of Settlement Approval Hearing to the Class in accordance with Schedule F. Pursuant to the Defendants' obligations in Section 4.9, the Defendants will pay the cost of this dissemination irrespective of whether or not the Settlement Agreement is approved, but if approved, the cost of this dissemination shall be subject to the Notice and Administration Costs maximum of \$500,000 (CAD). This notice will provide an opportunity for potential Class Members to object to the terms of the Settlement.



- 3.6 **Publication of the Notice of Settlement Approval.** After this Settlement Agreement has been approved by the Court, Class Counsel shall disseminate the Notice of Settlement Approval to the Class in accordance with Schedule F. Pursuant to Defendants' obligations in Section 4.9, Defendants will pay the cost of dissemination, subject to the Notice and Administration Costs to a maximum of \$500,000 (CAD).

#### Section 4 Settlement Program Benefits and Claims

- 4.1 **Applicable Currency.** Notwithstanding anything to the contrary, all dollar amounts provided herein, including all amounts due to Approved Claimants, are stated and payable in Canadian dollars.
- 4.2 **Payment of the Settlement Amount.**
- 4.2.1 Conditional upon the approval of this Settlement Agreement as provided herein and the dismissal of the Ontario Proceeding with prejudice and, as applicable, the release of the claims of the Class Members, Defendants agree to pay, or cause to be paid: (i) the Settlement Awards on a per Eligible Claimant basis on a claims-approval basis to the Account for disbursement by the Claims Administrator, provided (a) the Effective Date has passed, and (b) the Settlement Award is final and non-appealable within the Settlement Program; and (ii) Notice and Administration Costs.
- 4.2.2 The Parties understand and agree that the Defendants shall not be liable for, nor shall they be a proper party to any dispute related to any alleged harm or injury suffered by any member of the Class by reason of the use or alleged misuse of any of the Settlement Amount or of an erroneous disbursement or other action taken or failure to act with respect to any of the Settlement Amount.
- 4.2.3 An individual is eligible for recovery under this Settlement Agreement only if:
- 4.2.3.1 s/he is an Eligible Claimant or Principal Caregiver of an enrolled Eligible Claimant; and
- 4.2.3.2 s/he proves entitlement to recovery under this Settlement Agreement pursuant to the terms and documentation requirements of this Settlement Agreement.
- 4.2.4 Only Class Members who have submitted all necessary information and documentation to the Claims Administrator within the applicable Claims Period, proving they are an Eligible Claimant entitled to receive compensation under this Settlement Agreement, shall receive compensation under this Settlement Agreement. For all claimants, "necessary information" includes a completed Claim Form (Schedule A) and the information and documents described in Section 4.4.2.
- 4.2.5 The amount of recovery for any Eligible Claimant under Section 4.2.8 shall be established according to the patient's status as of the date the Class Member's Claim Form is initially filed with the Claims Administrator.

- 4.2.6 Any amount paid to an Approved Claimant under this Settlement Agreement has been paid as damages on account of alleged personal physical injuries or illness of the Approved Claimant, including physical injuries or illness resulting from alleged emotional harm.
- 4.2.7 The Defendants agree to pay amounts in accordance with the terms of this Settlement Agreement, in full satisfaction of all of the Released Claims against the Released Persons, contingent on dismissal of the claims of the certified class in the Ontario Proceeding.
- 4.2.8 The Class Members who are Eligible Claimants who become Approved Claimants shall be compensated as follows ("Settlement Awards"), subject to reduction as set forth in this Settlement Agreement, including Section 4.3, and less their respective share of any Class Counsel Fees that the Court may award to Class Counsel in accordance with Section 9:

**4.2.8.1 For Unilateral Claimants:**

- 4.2.8.1.1 Base Award: Subject to this Section 4.2, Class Members who have undergone a Unilateral Revision that is a Qualified Revision Surgery shall each receive a single award of \$110,000 (CAD) subject to the applicable reductions set forth in Section 4.3.
- 4.2.8.1.2 Out-of-Pocket Expenses: Subject to this Section 4.2, Class Members who have undergone an Unilateral Revision that is a Qualified Revision Surgery shall each receive a single award of up to a maximum of \$2,500 (CAD) for out-of-pocket expenses related to the Qualified Revision Surgery, and supported with documentary proof.
- 4.2.8.1.3 Enhancements: Subject to this Section 4.2 and Section 4.3, Class Members who have undergone an Unilateral Revision that is a Qualified Revision Surgery who have a claim for an Enhancement, including Income Loss, may receive additional funds in aggregate up to a maximum of \$65,000 (CAD) for qualified claims as set forth in Schedule H.

**4.2.8.2 For Bilateral Claimants:**

- 4.2.8.2.1 Base Award: Subject to this Section 4.2, Class Members who have undergone Bilateral Revisions that are Qualified Revision Surgeries shall each receive a single award of \$135,000 (CAD) subject to the applicable reductions set forth in Section 4.3.
- 4.2.8.2.2 Out-of-Pocket Expenses: Subject to this Section 4.2, Class Members who have undergone a Bilateral Revision that is a Qualified Revision Surgery shall each receive a single award of up to a maximum of \$2,500 (CAD) for out-of-pocket expenses

related to the Qualified Revision Surgery(ies), and supported with documentary proof.

- 4.2.8.2.3 **Enhancements:** Subject to this Section 4.2 and Section 4.3, Class Members who have undergone a Bilateral Revision and who have a claim for an Enhancement, including Income Loss, may receive additional funds in the aggregate up to a maximum of \$80,000 (CAD) as set forth in Schedule H.
- 4.2.8.3 **For Medically Precluded Claimants:** Class Members who are Medically Precluded Claimants shall each receive \$55,000 (CAD). Such award is not subject to any reductions as set forth in this Settlement Agreement and includes all claims by the Health Insurer. The Health Insurer shall provide to the Parties the necessary statutory consents and/or approvals to the settlement of that Class Member's claim. In addition, Medically Precluded Claimants are not entitled to any Enhancements.
- 4.2.8.4 **For the Representative Plaintiffs:** For the representative plaintiffs identified in Section D of the Recitals, such Plaintiffs shall each receive an honoraria of \$10,000 (CAD) in addition to any other Settlement Award they may be entitled to under this Settlement Agreement.
- 4.2.8.5 Class Members who underwent an Excluded Revision Surgery are not entitled to the compensation under this Settlement Agreement.
- 4.2.8.6 Class Members who are Unrevised Claimants as of the Last Eligible Date, other than in accordance with the Discretionary Extension, are not entitled to compensation under this Settlement Agreement.
- 4.2.8.7 Unless a Discretionary Extension is granted, Class Members whose Index Surgery occurred ten (10) years or more prior to the Revision Surgery on that same hip are not entitled to the compensation provided in this Section 4.2.
- 4.2.9 **For Principal Caregivers.** The Principal Caregiver shall receive a single award of up to a maximum of \$5,000 (CAD), if applicable and supported by a declaration signed by the Principal Caregiver as part of the Eligible Claimant's Claim Form. Only one award per Approved Claimant shall be issued for a Principal Caregiver who provided care for an enrolled Eligible Claimant who underwent a Qualified Revision Surgery.
- 4.2.10 **For Health Insurers.** Health Insurers shall receive \$15,000 (CAD) for each *Qualified Revision Surgery* that a Class Member who submits a proper and approved claim for recovery under this Settlement Agreement underwent in the Health Insurers' jurisdiction, and upon the Health Insurer providing to the Parties the necessary statutory consents and/or approvals to the settlement of that Class Member's claim.

4.2.11 **The Broadspire Program.** The program through Crawford & Company, Inc. (the "**Broadspire Program**") is a voluntary program that was created by Defendants and it is Defendants' unilateral right to determine when the Broadspire Program ends. Defendants have determined that once an Eligible Claimant enrolls in the Settlement Program, any benefits issued to such Claimant by Crawford & Company, Inc. through the Broadspire Program shall be terminated or otherwise no longer available. The Broadspire Program will also terminate for an Eligible Claimant who chooses not to enroll in the Settlement Program by the applicable Claims Period Deadline.

4.2.12 The Claims Administrator shall pay Class Counsel for Class Counsel Fees and Disbursements owing under Sections 9.1 through Section 9.2 from the Account. The Claims Administrator shall bill Defendants directly for the Administration Costs.

4.2.13 Once the Claims Administrator determines that all amounts owing under this Settlement Agreement have been paid, the Claims Administrator shall notify the Defendants and Class Counsel.

4.2.14 The Claims Administrator shall maintain the Account and shall not pay out funds from the Account in a manner inconsistent with the provisions of this Settlement Agreement except by Court order made on notice to, or on the consent of, the Defendants' Counsel and Class Counsel.

**4.3 Reductions to Settlement Payments.**

4.3.1 The following reductions shall be applied to all Settlement Awards under Section 4.2.8 to Approved Claimants prior to the calculation of any other reductions based on the length of time from the Index Surgery to the Qualified Revision Surgery ("**Implantation Length**"), and these reductions shall not be funded by Defendants but shall be retained by Defendants for Defendants' benefit:

<b><u>Implantation Length "X"</u></b>	<b><u>Amount of Reduction</u></b>
7 Years $\leq$ X < 8 Years	10%
8 Years $\leq$ X < 9 Years	20%
9 Years $\leq$ X < 10 years	30%

4.3.2 The following reductions shall be applied to all Settlement Awards under Section 4.2.8 to Approved Claimants due to age of the Approved Claimant at the time of the Index Surgery, and these reductions shall not be funded by Defendants but shall be retained by Defendants for Defendants' benefit:

Age at Index Surgery	Percent Reduction
Age $\geq$ 80	15%
Age $\geq$ 85	20%

4.3.3 The amount of reductions to settlement awards shall be calculated and applied by the Claims Administrator prior to requesting payment for approved Settlement Awards from Defendants in the reports set forth in Section 4.5.10.

**4.4 Filing Claims in the Settlement Program.**

4.4.1 The purpose of the documentation requirements with respect to claimants' entry into the Settlement Program is to obtain information and documentation to establish that a claimant is an Eligible Claimant and qualifies to become an Approved Claimant for a settlement payment.

4.4.2 In order to be compensated pursuant to the Settlement Program for a Settlement Award, one must be an Eligible Claimant and provide to the Claims Administrator, the following:

4.4.2.1 A completed Claims Form (Schedule A);

4.4.2.2 The Product Code/Lot Code, including product label stickers, and Contemporaneous Medical/Hospital Records sufficient to show the implantation for each Affected Product surgically implanted in the Eligible Claimant in Canada;

4.4.2.3 The Contemporaneous Medical/Hospital Records comprising the claimant's Discharge Summaries, and the Operative Reports pertaining to any Index Surgery, Qualified Revision Surgery, and any claim for an Enhancement;

4.4.2.4 For Claimants Revised after September 25, 2018 Only: The Contemporaneous Medical/Hospital Records demonstrating that the Revision Surgery involved one or more of the following: (i) an elevated cobalt level; (ii) an abnormal diagnostic scan associated with the tissue around the femoral implant related to the reasons underlying the Voluntary Recall; or (iii) intra-operative or pathologic confirmation of ALTR, ALVAL or tissue damage related to the reasons underlying the Voluntary Recall; and

4.4.2.5 Income and tax records if Income Loss is one of the Enhancements claimed.

- 4.4.2.6 Notwithstanding the above, the Claims Administrator shall have the discretion to compensate Eligible Class Members pursuant to the Settlement Program if the aforementioned records are not included if it is clear to the Claims Administrator or the Reconsideration Officer based on contemporaneous medical records that the criteria for eligibility have been met.
- 4.4.3 The deadline for filing claims in the Settlement Program shall be 5:00 p.m. Vancouver time on the last day of the applicable Claims Period to that Claimant, unless extended by written agreement of the Parties.
- 4.4.4 An Eligible Claimant who files a claim with the Settlement Program and submits all the required documentation and meets all the necessary criteria to the satisfaction of the Claims Administrator, or any reconsideration protocol, becomes an Approved Claimant.
- 4.4.5 It is the responsibility of each claimant to submit all documentation necessary to support his/her claim.

#### **4.5 Claims Handling and Settlement Payment Process.**

- 4.5.1 The administration and processing of claims of Class Members and the payment of funds into and from the Account shall be conducted by or under the supervision of the Claims Administrator with instructions from Defendants and Class Counsel acting reasonably and with input by the Court if necessary.
- 4.5.2 The determination of Eligible Claims shall be made by the Claims Administrator in accordance with Sections 4.2 through 4.4 and the Definitions of this Settlement Agreement.
- 4.5.3 The Defendants have the right to examine the supporting documentation for any claim submitted to the Claims Administrator, and Defendants may at their option choose to submit in writing to the Claims Administrator, with a copy to Class Counsel, reasons they believe that a claim is ineligible or its supporting documentation is deficient. The Claims Administrator shall establish a central repository of information submitted by claimants, which shall be accessible for this purpose.
- 4.5.4 In order to recover under this Settlement Agreement, including a claim for Enhancements, Class Members who are Eligible Claimants must mail or email a properly completed and executed Claim Form in the form attached as Schedule A and all supporting documentation such that they are received by the Claims Administrator no later than 5:00 p.m. Vancouver time on the last day of the applicable Claims Period. Claims that are emailed will be deemed submitted as of the date and time of the email and must be emailed no later than 5:00 p.m. Vancouver time on the last day of the applicable Claims Period. Claims that are mailed will be deemed submitted as of the postmark date and must be mailed no later than the last day of the applicable Claims Period.

- 4.5.5 Any form or other documentation required to be served or submitted under this Settlement Agreement shall be deemed timely (i) if delivered by mail (and not required to be delivered in some other fashion), if postmarked (or, in the absence of a postmark or if such postmark is illegible, if received) on or before the date by which it is required to be submitted under this Agreement; or (ii) if delivered by electronic mail, if the date and time of the email is on or before the date by which it is required to be submitted under this Agreement.
- 4.5.6 No later than 60 days from the date that the Claims Administrator receives a completed version of the claim form (*see* Schedule A to this Settlement Agreement) from a Class Member, the Claims Administrator shall notify the Class Member about whether he or she is an Approved Claimant who will receive payment under this Settlement Agreement, and if the Class Member will not receive payment, the reason why the claim for compensation was rejected, in whole or in part.
- 4.5.7 If the Claims Administrator determines that the materials submitted by a timely enrolled Class Member are deficient, the Claims Administrator shall notify the Class Member in writing of the deficiency and shall provide the Class Member with 90 days to rectify the deficiency by delivering further or amended materials, regardless of whether the last day of the applicable Claims Period has elapsed.
- 4.5.8 The Claims Administrator shall determine and certify, in its sole discretion, whether a claim for compensation under this Settlement Agreement has been properly made. The decision of the Claims Administrator regarding a Class Member's eligibility to recover under this Settlement Agreement shall be made according to the terms of this Settlement Agreement and shall be final and not subject to review. Reconsideration may be sought for all other decisions made by the Claims Administrator in connection with a Class Member's recovery under this Settlement by a Class Member or Defendants within the time frame and by following the Reconsideration Protocol outlined in Schedule I. A Claims Administrator's decision will be deemed received ten (10) days after it is mailed to a Class Member.
- 4.5.9 All reconsiderations will be decided by a Reconsideration Officer for decision based only on written submissions from the parties involved and the prior decision of the Claims Administrator. All decisions rendered by the Reconsideration Officer shall be final and not subject to further review or appeal.
- 4.5.10 Starting after the report in Section 4.5.12 is issued, on both the 15th and 1st day of each month, the Claims Administrator shall provide Defendants and Class Counsel a report, in such form and in such detail as Defendants and Class Counsel reasonably from time to time may specify, identifying those Approved Claimants whose claims for payment have been approved since the preceding report, if any, and the amount of each of their approved claim payments, and certifying those Settlement Awards in accordance with this Agreement. Within seven (7) Business Days following the receipt of such report, and assuming Defendants have not previously objected to its accuracy, Defendants will deposit or cause to be deposited into the Account an amount sufficient to pay the aggregate amount set forth in the award report.

- 4.5.11 After approving a claim for payment made by a Class Member, and after having received a deposit in the Account for the payment of the approved claim payment of that Approved Claimant, the Claims Administrator shall promptly pay the Approved Claimant or the Approved Claimant's legal representatives or counsel. However, payment under this Settlement Agreement shall not be made to an Approved Claimant until the Approved Claimant satisfies the requirements of Sections 4.2 and 4.4.
- 4.5.12 Within thirty (30) Business Days of the close of each of the respective Claims Periods, the Claims Administrator shall provide to Defence Counsel and to Class Counsel a report of the Approved Claims received by the Claims Administrator, including each Approved Claimant's name, date of his/her Qualified Revision Surgery, and his/her Claims Amount.
- 4.5.13 Class Members and Class Counsel agree to secure all authorizations and consents from Health Insurers necessary to facilitate settlement under this Settlement Agreement.
- 4.5.14 At the same time the Claims Administrator pays an Approved Claimant who is a Class Member, the Claims Administrator shall also remit from the Account the Class Counsel Fees and amounts under O. Reg. 771/92 section 8(4)(c)(ii) prescribed by Section 9 and any order of the Court to Class Counsel for Approved Claimants who are Class Members or their estate representatives.
- 4.6 **Administration of Agreement.** Except to the extent provided for in this Settlement Agreement, any disagreement as to the implementation and administration of this Settlement Agreement shall be determined by the Court on motion brought by the Parties, or any of them.
- 4.7 **Total Amounts Payable by the Released Persons.** The Defendants agree to pay reasonable Notice and Administration Costs up to a maximum of \$500,000 (CAD) and the final and approved settlement awards of all Approved Claimants in settlement of all claims by the Releasing Persons against the Released Parties in respect of the Released Claims. Class Counsel Fees, reimbursement to the Fonds, applicable taxes and any unclaimed balance owing to the Fonds following the Last Eligible Date shall be paid from the Settlement Amount. Under no circumstances shall the Defendants' obligations under this Settlement Agreement, including the court approval process and settlement administration, require payment of any amounts in excess of the amounts agreed upon in this Settlement Agreement.
- 4.8 **Releases.**
- 4.8.1 The Approval Order approving this Settlement Agreement shall provide a release, whereby the Releasing Persons unconditionally and forever release, acquit, remise and forever discharge the Released Parties from the Released Claims and agree not to make any claim, or take or continue any action, investigation, or other proceedings in any forum arising out of or relating to the subject matter of the Released Claims against any other person, corporation, or entity including any public authority or



statutory body (including, without limitation, any health care professionals, health care providers, health care facilities, pharmacies, public authority including Her Majesty the Queen in right of Canada, or any distributor or supplier of the Affected Product) which might claim damages and/or contribution and indemnity and/or other relief under the provisions of the Negligence Act, R.S.O. 1990 c. N-1 or other comparable provincial legislation and any amendments thereto, the common law, equity, Quebec Civil Law or any other statute, for any relief whatsoever, including relief of a monetary, declaratory or injunctive nature, from one or more of the Released Parties.

- 4.8.2 This Settlement Agreement shall extinguish any liens, subrogation claims, or other claims by persons or entities arising out of or related to expenses for medical services or disability benefits provided to Releasing Persons, whether by right of subrogation, assignment, contract, statute, regulation, or otherwise, relating to or arising from the prescription, sale, purchase, implantation, use, removal and/or revision of an Affected Product.

**4.9 Payment of Notice and Administration Costs.**

- 4.9.1 The Claims Administrator shall bill Defendants for reasonable Notice and Administration Costs up to a maximum of \$500,000 (CAD).
- 4.9.2 The Account shall be used by the Claims Administrator to (a) receive Settlement Award payments from Defendants on a claims-qualifying basis, (b) make Settlement Award payments from the Account to or for the benefit of Approved Claimants, (c) reimburse disbursements made by the Fonds, and (d) pay Class Counsel Fees and Disbursements or other Class Counsel Fees and Disbursements owing under Section 9.1.1 from the Account.

**4.10 Appointment and Role of Claims Administrator.**

- 4.10.1 The Parties will agree upon a Claims Administrator to be appointed by the Court for the purpose of administering the Settlement. The Claims Administrator shall be subject to removal by the Court for cause.
- 4.10.2 The Claims Administrator shall make a determination as to whether each Class Member who seeks payment under this Settlement Agreement is an Approved Claimant based on the documentation submitted before the expiration of the applicable Claims Period by that Class Member. If such person is an Approved Claimant, the Claims Administrator shall determine the amount of funds due to the Approved Claimant under Section 4 and Schedule H.
- 4.10.3 The Claims Administrator shall sign and adhere to a confidentiality statement, in a form satisfactory to the Parties, by which it agrees to keep confidential any information concerning Class Members or Defendants. Further, the Claims Administrator shall institute and maintain procedures to ensure that the identity of all Class Members and all information regarding any claims and submissions will be kept strictly confidential.

- 4.10.4 The Claims Administrator shall administer all monies payable under this Settlement Agreement, except as specifically provided for herein, and process all claims of Class Members in accordance with the terms of this Settlement Agreement.
- 4.10.5 The Claims Administrator shall offer its services in both English and French.
- 4.10.6 The Claims Administrator shall report on a monthly basis to Class Counsel and Defendants' Counsel on the number of claims received in that month and the decisions made by it in respect of any claim, or on such other reporting interval as may be agreed in writing between Class Counsel and the Defendants. Such reports will include the name of each Approved Claimant, and the category and amount of each payment to be deposited into and made from the Account.
- 4.10.7 The Claims Administrator shall retain all records relating to the claim of each Class Member. Defendants' Counsel, Defendants, and the Released Persons, as well as their respective insurers, may inspect the Claims Administrator's records. Any party inspecting the Claims Administrator's records under this paragraph shall maintain the confidentiality of the records to the extent necessary to protect the identity and privacy of the Class Members.
- 4.10.8 All submissions, requests, or motions made by the Claims Administrator to the Court must be served at least 15 days prior to the proposed date for the hearing of the request or motion.

## **Section 5**

### **Settlement Amount and Accrued Interest**

- 5.1 **Settlement Distribution.** Any Settlement Amounts held by the Claims Administrator shall be held in trust for the benefit of Class Members who are Approved Claimants in the Account, and shall only be paid to Approved Claimants in accordance with the provisions of this Settlement Agreement or as otherwise authorized herein.
- 5.2 **Monies in the Account.**
- 5.2.1 In no event shall the Defendants have any responsibility, financial obligations, or liability whatsoever with respect to the investment, distribution, use, or administration of monies in the Account, including, but not limited to, the costs and expenses of such investment, distribution, use and administration, Class Counsel Fees, and reimbursement to the Fonds, except as otherwise provided for in Sections 4 and 9.1.
- 5.2.2 The funds payable under this Settlement Agreement that Defendants are required to submit to the Claims Administrator under this Settlement Agreement shall be deposited into the Account. The Claims Administrator shall distribute payments under this Settlement Agreement from the Account under the supervision of the Court. Funds deposited into the Account shall be maintained and invested in a manner consistent with that of a prudent and reasonable administrator.

- 5.2.3 In the event that there are any funds remaining in the Account after payment of all Approved Claims, Notice and Administration Costs, Class Counsel Fees and Disbursements, and reimbursement to the Fonds, such surplus amount shall be remitted to Defendants, after paying the Fonds what is owed in accordance with Section 1(1) of the *Règlement sur le pourcentage prélevé par le Fonds d'aide aux actions collectives*.
- 5.2.4 Defendants shall retain a reversionary interest in all funds held in the Account and interest earned on the funds. If any funds remain in the Account 365 days after the expiration of the respective Claims Periods, those funds and any interest accrued shall be immediately returned to Defendants upon written request to the Claims Administrator (copy to Class Counsel), less any funds that have been approved for payment to an Approved Claimant but have not yet been paid out.

### 5.3 Taxes and Interest.

- 5.3.1 All interest earned on funds in the Account shall become and remain part of the Account.
- 5.3.2 All funds held by the Claims Administrator shall be deemed and considered to be *in custodia legis* of the Court and shall remain subject to the jurisdiction of the Court until such time as such funds are distributed pursuant to the Settlement Agreement and/or further order of the Court.
- 5.3.3 All taxes payable on any interest that accrues on the funds in the Account shall be the responsibility of the Class. The Claims Administrator, in consultation with Class Counsel, shall be solely responsible to fulfill all tax reporting and payment requirements arising from the amounts held in the Account, including any obligation to report taxable income and make tax payments. All taxes (including interest and penalties) due, with respect to the income earned by the amounts held in the Account, shall be paid from the Account.
- 5.3.4 The Defendants shall have no responsibility to make any tax filings relating to the Account, to pay tax on any income earned by the funds in the Account or pay any taxes on the monies in the Account, unless and only to the extent that such funds are returned to Defendants.

## Section 6 Objections

### 6.1 Procedure to Object.

- 6.1.1 A Class Member may object to the approval of the Settlement by sending a written objection by pre-paid mail, courier, fax, or email to Class Counsel. Class Counsel is required to forward all objections to Defendants' Counsel within 48 hours after receiving an objection.

- 6.1.2 Objections must be received before 5:00 p.m. Toronto time on a date that is fourteen (14) days before the date of the Settlement Approval Hearing.
- 6.1.3 A Class Member who wishes to object to the approval of the Settlement shall state in his/her objection:
  - 6.1.3.1 The full name, current mailing address, fax number, telephone number, and email address of the person who is objecting;
  - 6.1.3.2 A brief statement of the nature and reasons for the objection;
  - 6.1.3.3 A declaration that the person believes he or she is a member of the Class and the reason for that belief including, if available, the reference/catalogue and lot numbers of his/her Affected Product;
  - 6.1.3.4 Whether the person intends to appear at the Settlement Approval Hearing or intends to appear by counsel, and, if by counsel, the name, address, telephone number, fax number, and email address of counsel; and
  - 6.1.3.5 A declaration under the penalty of perjury that the foregoing information is true and correct.
- 6.1.4 Class Counsel shall, no later than three (3) days before the date of the Settlement Approval Hearing, report to the Court, by affidavit, with a copy to counsel for the Defendants, the names of persons who objected and copies of any objections.

## Section 7

### Releases and Dismissals

- 7.1 **Release of Released Claims Against Released Persons.** Upon the Effective Date, and in consideration of the payments of the amounts required under this Settlement Agreement and for other valuable consideration set forth in this Settlement Agreement, the Releasing Persons forever and absolutely release the Released Persons from the Released Claims, including but not limited to all claims, actions, causes of action, suits, debts, duties, accounts, bonds, covenants, contracts, and demands whatsoever that were asserted, or could have been asserted, and that are the subject of this Settlement Agreement. For the consideration provided herein, the Releasing Persons agree not to make any claim, or take or continue any proceedings arising out of or relating to the subject matter of the Released Claims, against any other person, corporation, or entity (including, without limitation, any health care professionals, health care providers, and hospitals or other health care facilities) that might claim damages and/or contribution and indemnity and/or other relief under the provisions of the Negligence Act or other comparable provincial legislation and any amendments thereto, the common law, equity, Quebec civil law, or any other statute, for any relief whatsoever, including relief of a monetary, declaratory, or injunctive nature, from one or more of the Releasees.
- 7.2 **No Further Claims.** The Releasing Persons shall not now or hereafter institute, continue, maintain, or assert, either directly or indirectly, whether in Canada or elsewhere, on their

own behalf or on behalf of, or as part of, any class or any other person, any action, suit, cause of action, claim, or demand against any Released Persons, or against any other person who may claim contribution or indemnity from any Released Person in respect of any Released Claim or any matter related thereto. The Parties agree that no Class Members shall recover, directly or indirectly, any sum from Defendants or Released Persons other than the sum authorized under this Settlement Agreement in connection with the Affected Product and Qualified Surgery.

- 7.3 **Dismissal of the Proceedings.** The Ontario Proceeding shall be dismissed with prejudice and without costs as against the Defendants. All lawsuits of Class Members against any Released Persons relating in any way to the Released Claims will be dismissed with prejudice without costs.

## **Section 8**

### **Termination of Settlement Agreement**

#### **8.1 Right of Termination.**

8.1.1 The Defendants shall have the right, in their sole discretion, to terminate this Settlement Agreement if:

8.1.1.1 the Court declines to approve this Settlement Agreement or any term or part thereof deemed material by Defendants;

8.1.1.2 any order approving this Settlement Agreement does not become a Final Order;

8.1.1.3 any order dismissing the Ontario Proceeding does not become a Final Order;

8.1.1.4 the form and content of any of the Final Orders approved by the Court do not materially comply with the terms of this Settlement Agreement; or

8.1.1.5 the Health Insurers do not accept this Settlement Agreement or any material term or part thereof and provide or commit to provide statutory consents or approvals.

8.1.2 To exercise a right of termination, the Defendants shall deliver a written notice of termination to Class Counsel within seven (7) days of the event. Upon delivery of such a written notice, this Settlement Agreement shall be terminated and, except as provided for in Sections 8.2 and 8.3, it shall be null and void and have no further force or effect, shall not be binding on the Parties, and shall not be used as evidence or otherwise in any litigation.

- 8.2 **If Settlement Agreement Is Terminated.** If this Settlement Agreement is not approved by the Court, is terminated in accordance with its terms, or otherwise fails to take effect for any reason:

- 8.2.1 Any order approving this Settlement Agreement shall be set aside and declared null and void and of no force or effect, and anyone shall be estopped from asserting otherwise;
  - 8.2.2 All negotiations, statements, and proceedings relating to the settlement and the Settlement Agreement shall be deemed to be without prejudice to the rights of the Parties, and the Parties shall be deemed to be restored to their respective positions existing immediately before it was executed; and
  - 8.2.3 All funds in the Account (including accrued interest) shall be returned to Defendants' Counsel within 10 days after the date of termination.
- 8.3 **Survival of Provisions after Termination.** If this Settlement Agreement is not approved by the Court, is terminated in accordance with its terms, or otherwise fails to take effect for any reason, the provisions of this Section and Sections 8.2 and 11 and the Recitals, Definitions, and Schedules applicable thereto shall survive the termination and continue in full force and effect.

## **Section 9**

### **Legal Fees and Disbursements**

#### **9.1 Class Counsel Fees.**

- 9.1.1 The Defendants shall make a single contribution toward reasonable Class Counsel Fees and Disbursements in the amount of \$550,000 (CAD) inclusive of all applicable taxes, pending Court approval.
- 9.1.2 Additional Class Counsel Fees and Disbursements payable by Approved Claimants, which may be determined and approved by the Court, shall be deducted by the Claims Administrator from the settlement awards to Approved Claimants and paid to Class Counsel. For certainty, this Settlement Agreement is not conditional on the Court's approval of any Class Counsel Fees and Disbursements Class Counsel may seek in accordance with Section 9.2.1 below, and in no circumstances shall the Defendants be required to contribute more than \$550,000 (CAD) inclusive of all applicable taxes to Class Counsel Fees and Disbursements, subject to Court approval.

#### **9.2 Procedure.**

- 9.2.1 Class Counsel will bring motions, with notice to Defendants' Counsel, to the Court for determination and approval of Class Counsel Fees and Disbursements payable by the Class Members in accordance with Section 9.1.2. In any such Court application, Class Counsel shall serve and file documentation that supports the amount of Class Counsel Fees claimed. The Defendants shall not take a position on Class Counsel's motions for determination and approval of Class Counsel Fees and Disbursements.

- 9.2.2 Class Counsel Fees and Disbursements payable pursuant to Section 9.1.1 may be paid out of the Account only after Class Counsel obtains the approval of the Court. Payment of Additional Class Counsel Fees under Section 9.1.2 in respect of Class Members is subject to approval of the Court.
- 9.2.3 Class Members who have retained, or do retain, lawyers to assist them in making their individual claims in this Settlement shall be responsible for the legal fees and expenses of such lawyers.
- 9.2.4 Class Members are responsible for their own costs in completing their Claim Form, retrieving and producing medical and hospital records to the Claims Administrator, and otherwise filing and perfecting their claims under this Settlement Agreement. Defendants are not responsible for these costs and expenses.
- 9.2.5 Defendants shall make a deposit in amounts not to exceed the amounts set forth in Section 9.1.1 to enable the Claims Administrator to pay approved Class Counsel Fees and Disbursements up to the amounts set forth in Section 9.1.1 within 14 days of the Court's approval of Class Counsel Fees and Disbursements. However, if the award of Class Counsel Fees and Disbursements is appealed, Class Counsel agrees to return to the Account such Class Counsel Fees and Disbursements paid from the Account until such award is final without the possibility of further appeal at which time the payment will be returned to Class Counsel. If, following an appeal, the final award of Class Counsel Fees and Disbursements is less than \$550,000 (CAD), the excess amount shall be returned to Defendants by the Claims Administrator and the remaining amount of the initial payment to Class Counsel pursuant to this subparagraph shall be returned to Class Counsel.
- 9.3 **Payment of Reconsideration-Related Fees and Costs.** Payment of all reasonable and necessary fees and costs charged by those persons serving as Reconsideration Officer in connection with any reconsideration initiated by a Class Member will be made by the Defendants subject to the Notice and Administration Costs maximum of \$500,000 (CAD).

## **Section 10**

### **Administration and Implementation**

- 10.1 **Mechanics of Administration.** Except to the extent provided for in this Settlement Agreement, the mechanics of the implementation and administration of this Settlement Agreement shall be determined by the Court on motion brought by the Parties, or any one of them.
- 10.2 **Notices Required.**
- 10.2.1 The Class shall be given notice of:
- 10.2.1.1 The hearing at which the Court will be asked to approve the Settlement Agreement; and
- 10.2.1.2 The Court order approving this Settlement Agreement, if applicable.

10.2.2 Class Counsel and Defendants' Counsel will jointly prepare such respective Notices as may be required, substantially in the forms attached as Schedules D and E, respectively, as well as a plan for dissemination of the Notice of Settlement Approval Hearing and the Notice of Settlement Approval at Schedule F, if applicable. Counsel acknowledge that all Notices and the respective plans for the dissemination of two Notices must be approved by the Court. No notices shall be disseminated until such time as they are approved by the Court.

## **Section 11**

### **No Admission of Liability**

- 11.1 The Parties agree that whether or not this Settlement Agreement is approved by the Court, or is terminated, this Settlement Agreement and anything contained herein, and any and all negotiations, documents, discussions, and proceedings associated with this Settlement Agreement, and any action taken to carry out this Settlement Agreement, shall not be deemed, construed, or interpreted to be an admission of any violation of any statute or law, or of any wrongdoing or liability by the Releasees, or of the truth of any of the claims or allegations made in the Ontario Proceeding or in any other pleading filed by the Plaintiffs.
- 11.2 The Parties further agree that whether or not this Settlement Agreement is approved by the Court, or is terminated, neither this Settlement nor any document relating to it shall be offered in evidence in any action or proceeding in any court, agency, or tribunal, except to seek court approval of this Settlement Agreement or to give effect to and enforce the provisions of this Settlement Agreement.

## **Section 12**

### **Miscellaneous**

#### **12.1 Motions for Directions.**

12.1.1 The Plaintiffs, Class Counsel, Claims Administrator, or the Defendants may apply to the Court for directions in respect of the implementation and administration of this Settlement Agreement.

12.1.2 All motions contemplated by this Settlement Agreement, including applications to the Court for directions, shall be on notice to the Parties.

12.2 **Released Persons Have No Liability for Administration.** The Released Persons shall have no responsibility for and no liability whatsoever with respect to the implementation and administration of this Settlement Agreement.

12.3 **Headings, etc.** In this Settlement Agreement, the division of the Settlement Agreement into Sections and the insertion of headings are for convenience of reference only and shall not affect the construction or interpretation of this Settlement Agreement. A reference or cross-reference to a particular Section is a reference to a section of this Settlement Agreement unless stated otherwise. The terms "this Settlement Agreement," "the Settlement Agreement," "hereof," "hereunder," "herein," "hereto," "below," and similar expressions



refer to this Settlement Agreement and not to any particular section or portion of this Settlement Agreement unless so specifically stated.

- 12.4 **Ongoing Jurisdiction.** The Court shall retain exclusive jurisdiction over all matters relating to the implementation and enforcement of this Settlement Agreement.
- 12.5 **Governing Law.** This Settlement Agreement shall be governed by and construed and interpreted in accordance with the laws of the Province of Ontario.
- 12.6 **Entire Agreement.** This Settlement Agreement and the Schedules attached hereto constitute the entire agreement among the Parties, and supersede any and all prior and contemporaneous understandings, undertakings, negotiations, representations, communications, promises, agreements, agreements in principle, and memoranda of understanding in connection herewith. The Parties agree that they have not received or relied on any agreements, representations, or promises other than as contained in this Settlement Agreement. None of the Parties shall be bound by any prior obligations, conditions, or representations with respect to the subject matter of this Settlement Agreement, unless expressly incorporated herein. This Settlement Agreement may not be modified or amended except in writing and on consent of all Parties hereto, and any such modification or amendment must be approved by the Court.
- 12.7 **Survival.** The representations and warranties contained in this Settlement Agreement shall survive its execution and implementation.
- 12.8 **Counterparts.** This Settlement Agreement may be executed in counterparts, all of which taken together will be deemed to constitute one and the same agreement, and a facsimile signature shall be deemed an original signature for purposes of executing this Settlement Agreement. This Settlement Agreement may be delivered and is fully enforceable in either original, faxed, or other electronic form provided that it is duly executed.
- 12.9 **Negotiated Agreement.** This Settlement Agreement has been the subject of negotiations and discussion among the Parties, each of which has been represented and advised by competent counsel, so that any statute, case law, or rule of interpretation or construction that would or might cause any provision to be construed against the drafter of this Settlement Agreement shall have no force and effect. The Parties further agree that the language contained or not contained in previous drafts of this Settlement Agreement, or any agreement in principle, shall have no bearing upon the proper interpretation of this Settlement Agreement.
- 12.10 **Language.** The Parties acknowledge that they have required and consented that this Settlement Agreement and all related documents be prepared in English; *les parties reconnaissent avoir exigé que la présente convention et tous les documents connexes soient rédigés en anglais.*
- 12.11 **Dates.** Dates referred to in this Settlement Agreement may be altered with the written consent of the Parties and with the approval of the Court.

- 12.12 French Translation.** The Parties acknowledge that they also have required that the Settlement Agreement, including Schedules, be prepared in French. The English version of the Settlement Agreement is authoritative in Ontario (and is authoritative as to all Class Members in any province or territory of Canada), and the French and English versions of this Settlement Agreement have equal force in Quebec for Class Members who reside in Quebec. A French translation of the Settlement Agreement and all notices pursuant to this Settlement Agreement shall be paid for by the Defendants, subject to the maximum of \$500,000 (CAD) for Notice and Administration Costs.
- 12.13 Confidentiality.** The Parties agree that no public statements shall be made regarding these Proceedings or their settlement that are in any way inconsistent with the terms of this Settlement Agreement. In particular, the Parties agree that any public statements regarding these Proceedings will indicate only that the settlement has been negotiated and agreed by the parties and approved by the Court without any admissions or findings of liability or wrongdoing and without any admissions or conclusions as to the truth of any of the facts alleged in the Proceedings, all of which are specifically denied. The Parties further agree that existence and terms of this Settlement Agreement shall remain confidential until a Proposed Court Order on Notice of Hearing for Settlement Approval has been submitted to the Court.
- 12.14 Recitals.** The recitals to this Settlement Agreement are true and form part of this Settlement Agreement.
- 12.15 Schedules.** The Schedules annexed hereto form part of this Settlement Agreement and are:
- 12.15.1 Schedule A – Sample Claim Form
  - 12.15.2 Schedule B – Proposed Court Order on Notice of Hearing for Settlement Approval
  - 12.15.3 Schedule C – Proposed Court Order on Approval of Settlement Agreement
  - 12.15.4 Schedule D – Proposed Explanation Letter and Form of Notice of Settlement Approval Hearing
  - 12.15.5 Schedule E – Form of Notice of Settlement Approval
  - 12.15.6 Schedule F – Plan for Dissemination of Notice of Settlement Approval Hearing and Notice of the Order Approving the Settlement
  - 12.15.7 Schedule G – Proposed Court Order Regarding Distribution of Notices of Approval Hearing and Settlement Approval
  - 12.15.8 Schedule H – List of Enhancements and Corresponding Definitions and Payment Amounts Under the Enhancements Benefit Program
  - 12.15.9 Schedule I – Reconsideration Protocol

12.15.10 Schedule J – Voluntary Recall Notice

**12.16 Acknowledgements.** Each of the Parties hereby affirms and acknowledges that:

- 12.16.1 He, she, or a representative of the Party with the authority to bind the Party with respect to the matters set forth herein has read and understood the Settlement Agreement;
- 12.16.2 The terms of this Settlement Agreement and the effects thereof have been fully explained to him, her, or the Party's representative by his, her, or its counsel;
- 12.16.3 He, she, or the Party's representative fully understands each term of this Settlement Agreement and its effect; and
- 12.16.4 No Party has relied upon any statement, representation, or inducement (whether material, false, negligently made, or otherwise) of any other Party with respect to the first Party's decision to execute this Settlement Agreement.

**12.17 Authorized Signature.** Each of the undersigned represents that he or she is fully authorized to enter into the terms and conditions of, and to execute, this Settlement Agreement.

**12.18 Notice.** Where this Settlement Agreement requires a Party to provide notice or any other communication or document to another, such notice, communication, or document shall be provided by email, facsimile, or letter by overnight delivery to the representatives for the Party to whom notice is being provided, as identified below:

12.18.1 For Plaintiffs and Class Counsel:

Jonathan Ptak  
Koskie Minsky LLP  
20 Queen Street West, Suite  
900, Box 52  
Toronto, ON M5H 3R3  
Telephone: 416-977-8353  
Facsimile: 416-977-3316  
www.kmlaw.ca

Doug Lennox  
Klein Lawyers  
100 King Street West, Suite  
5600  
Toronto, ON M5X 1C9  
Telephone: 416-506-1944  
Facsimile: 416-506-0601  
www.callkleinlawyers.com

Colin Stevenson  
Stevenson Whelton LLP  
Barristers & Solicitors  
15 Toronto Street, Suite 200  
Toronto, ON M5C 2E3  
Telephone: 416-599-7900  
Facsimile: 416-599-7910  
www.swlawyers.ca

12.18.2 For Defendants and Defendants' Counsel:

Gordon McKee  
BLAKE, CASSELS & GRAYDON LLP  
199 Bay Street  
Suite 4000, Commerce Court West  
Toronto ON M5L 1A9  
Canada  
Telephone: 416-863-2400  
Email: gordon.mckee@blakes.com

Kim M. Catullo  
GIBBONS P.C.  
One Gateway Center  
Newark, New Jersey 07102-5310  
United States of America  
Telephone: 212-613-2000  
Email: kcatullo@gibbonslaw.com

WHEREFORE, the Parties have executed this Settlement Agreement on the dates provided below.

**PLAINTIFF AND CLASS COUNSEL:**

By: 

Jonathan Ptak  
Koskie Minsky LLP  
20 Queen Street West, Suite 900,  
Box 52  
Toronto, ON M5H 3R3  
Telephone: 416-977-8353  
Facsimile: 416-977-3316  
www.kmllaw.ca

By: 

Doug Lemox  
Klein Lawyers  
100 King Street West, Suite 5600  
Toronto, ON M5X 1C9  
Telephone: 416-506-1944  
Facsimile: 416-506-0601  
www.callkleinlawyers.com

Dated: May 2, 2019

Dated: May 2, 2019

By: 

Colin Stevenson  
Stevenson Whelton LLP  
Barristers & Solicitors  
15 Toronto Street, Suite 200  
Toronto, ON M5C 2E3  
Telephone: 416-599-7900  
Facsimile: 416-599-7910  
www.swlawyers.ca

Dated: May 2, 2019

**DEFENDANTS:**

**Stryker Canada LP, Stryker Canada Corp.,  
Stryker Canadian Management Inc.,  
Howmedica Osteonics Corporation,  
and Stryker Corporation**

By: Michael D. Carter

Dated: May 2, 2019

SCHEDULE A

SAMPLE CLAIM FORM

**Stryker Rejuvenate Modular Hip Implant Class Action**

*NOTE: The claim form included in this Schedule A is a sample claim form. You can obtain the final claim form by contacting the Claims Administrator by email at [●] or by calling its toll-free hotline at [●]. The Claims Administrator will not accept this sample claim form as a valid enrollment form.*

**For Claimants Revised before [the Effective Date] and for Medically Precluded Claimants:** This form must be completed and returned to the Claims Administrator no later than 210 days from the date of the Claims Administrator's first mailing of the Notice of Settlement Approval and continuing until 210 days thereafter.

**For Claimants Revised on or after [the Effective Date]:** This form must be completed and returned to the Claims Administrator no later than ninety (90) days after your Qualified Revision Surgery or 60 days after July 31, 2022, whichever date is earlier.

I am making a claim either myself or through my lawyer:

- ☐ as a Claimant who was implanted with the Stryker Rejuvenate Modular Hip Implant (the "Rejuvenate Modular").
- ☐ as the Representative (a person who is the legal representative of a Claimant who is deceased or under a legal disability) of a Claimant.

If you have any questions or need assistance completing this form, you may contact the Claims Administrator by email at [●] or by calling its toll-free hotline at [●]. You may also contact Class Counsel at [●].

**Section A: Claimant Information**

First Name

Middle

Last Name

Date of Birth (mm/dd/yyyy)

Gender: ☐ Male ☐ Female

Address

City

Province/Territory

Postal Code

Daytime Phone Number

Cellular Phone Number

Email

Current Provincial Health Insurance Number ("PHN")

Did the Claimant's province of residence change since the time that the Claimant received the Rejuvenate Modular?

☐ Yes ☐ No

If you checked "Yes," please list the Claimant's other province(s) of residence, the date(s) of residence, and his/her Provincial Health Insurance Number(s) for those province(s):

<b>Section B: Personal Representative</b>
---

Are you completing this form as someone with the legal capacity to act on behalf of the Claimant (*i.e.*, an individual with power of attorney, an estate representative, etc.)?

☐ Yes ☐ No

If "Yes," please complete the remainder of Section B with information about yourself. If "No," please skip to Section C.

First Name

Middle

Last Name

Date of Birth (mm/dd/yyyy)

Address

City

Province/Territory

Postal Code

Email

Date of Death of the Claimant (if applicable)  
(mm/dd/yyyy)

Daytime Phone Number

Cellular Phone Number

**Relationship to Claimant:**

Please attach the documents that grant you the legal authority to act on behalf of the Claimant to this form (i.e. Power of Attorney, Last Will and Testament, Letters of Administration, etc.). If the Claimant is deceased, please also attach a copy of the Claimant's death certificate to this form.

☐ Power of Attorney

☐ Certificate of Incapacity

☐ Letters of Administration

☐ Will

☐ Death Certificate

☐ Grant of Probate

☐ Other. Please explain \_\_\_\_\_

<b>Section C: Lawyer Information (if represented by a lawyer)</b>
---

Lawyer Last Name

Lawyer First Name

Name of Law Firm



Address

Phone Number

Email

**Section D: Rejuvenate Modular Implant Surgery Information**

This section is for a Claimant who was implanted with a Rejuvenate Modular and is making a claim as *either* a Qualified Revision Surgery Claimant (i.e. if your Rejuvenate Modular has been revised in accordance with the Settlement Agreement) *or* a Medically Precluded Claimant. Please complete the information in this Section as applicable.

Claim Type: ☐ Qualified Revision Surgery ☐ Medically Precluded

Location of the Implant: ☐ Right Hip Only ☐ Left Hip Only ☐ Both Left Hip and Right Hip

**Right Hip**

Implant Date (Right)

(mm/dd/yyyy)

Name of Hospital

Surgeon

**Left Hip**

Implant Date (Left)

(mm/dd/yyyy)

Name of Hospital

Surgeon

**Note: If you checked "Qualified Revision Surgery", complete Sections E – G as applicable. If you checked "Medically Precluded", please skip to Section J.**

### Required Submissions

In order to enroll in the Settlement Program, you must submit the following documents with your Claim Form:

- ☐ Manufacturer/product stickers for the Rejuvenate Modular for the device implanted into the Claimant. Only in the event product stickers are not available, please submit the electronic implant log from your Index Surgery.
- ☐ A copy of the implantation surgery operative report and discharge summary related to the hip(s) at issue.

### Section E: Revision Information (if applicable)

If the Claimant underwent a Revision Surgery to remove a Rejuvenate Modular, please select one of the following choices that apply to your claim and complete the following information.

Has the Claimant undergone a Revision Surgery(ies) to remove the Rejuvenate Modular?

☐ Yes ☐ No

If you checked "No," please skip to Section J below. If you checked "Yes," please complete this Section E.

Location of Revision: ☐ Right Hip Only ☐ Left Hip Only ☐ Both Left Hip and Right Hip

#### Right Hip

Revision Date (Right)

(mm/dd/yyyy)

Name of Hospital

Surgeon (if different  
from implanting  
surgeon identified in  
Section D)

#### Left Hip

Revision Date (Left)

(mm/dd/yyyy)

Name of Hospital:

Surgeon (if different  
from implanting  
surgeon identified in  
Section D)

If you have been revised after September 25, 2018, please check below the reason for your Revision Surgery (check all that apply):

- ☐ Elevated cobalt level.
- ☐ Abnormal diagnostic scan of surrounding tissue related to the reasons underlying the Voluntary Recall.
- ☐ Intra-operative or pathologic confirmation of adverse local tissue reaction ("ALTR"), aseptic lymphocyte dominated vasculitis-associated lesion ("ALVAL"), or tissue damage related to the reasons underlying the Voluntary Recall.

<b>Required Submissions</b>
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In order to enroll in the Settlement Program and submit a claim for a Qualified Revision Surgery, you must submit the following documents with your Claim Form:

- ☐ A copy of the Revision Surgery operative report and discharge summary related to the hip(s) at issue.
- ☐ Manufacturer/product stickers identifying the devices and hardware implanted during the Revision Surgery(ies). Only in the event product stickers are not available, please submit the electronic implant log from your Revision Surgery(ies).
- ☐ **For Claimants Revised after September 25, 2018:** A copy of Contemporaneous Medical Records that support the reason for your revision surgery was either: (i) an elevated cobalt level; (ii) an abnormal diagnostic scan of surrounding tissue related to the reasons underlying the Voluntary Recall; and/or (iii) intra-operative or pathologic confirmation of adverse local tissue reaction ("ALTR"), aseptic lymphocyte dominated vasculitis-associated lesion ("ALVAL"), or tissue damage related to the reasons underlying the Voluntary Recall.

## Section F: Enhancements

This section is for a Claimant who has undergone a Qualified Revision Surgery(ies) and qualifies for one of the below-listed Enhancements. All Enhancement claims are subject to an aggregate cap of \$65,000 (CAD) for qualifying Unilateral Revision Claimants and \$80,000 (CAD) for qualifying Bilateral Revision Claimants, including Income Loss in Section I below. Note that Medically Precluded Claimants are not entitled to Enhancements under the Settlement Program.

Check each category for which the Claimant believes s/he is entitled to compensation and for which s/he is submitting an application. If the Claimant is seeking an Income Loss Enhancement, s/he must complete Section G.

### Enhancement Category

#### Category I: Dislocation

- |   |                          |
|---|--------------------------|
| Dislocation – Closed Reduction  | <input type="checkbox"/> |
| Dislocation – Open Reduction  | <input type="checkbox"/> |
| Dislocation – Open Reduction with Conversion to a Constrained Component | <input type="checkbox"/> |

#### Category II: Blood Clot

- |            |                          |
|------------|--------------------------|
| Blood Clot | <input type="checkbox"/> |
|------------|--------------------------|

#### Category III: Infection

- |   |                          |
|---|--------------------------|
| Infection-Related Open Surgical Procedure | <input type="checkbox"/> |
| Infection-Related Non-Surgical Treatment  | <input type="checkbox"/> |

#### Category IV: Events Associated with Qualified Revision Surgery or Re-Revision Surgery

- |  |                          |
|--|--------------------------|
| Osteotomy                                    | <input type="checkbox"/> |
| Intraoperative Femur Fracture with Osteotomy | <input type="checkbox"/> |

Intraoperative Femur Fracture without Osteotomy ☐

Surgical Repair/Reattachment of a Damaged Abductor Muscle Complex ☐

**Category V: Re-Revision Surgery**

Re-Revision Surgery – First Re-Revision ☐

Re-Revision Surgery – Second Re-Revision ☐

**Category VI: Additional Surgery**

Additional Surgery ☐

**Category VII: Foot Drop**

Foot Drop ☐

**Category VIII: Myocardial Infarction**

Myocardial Infarction ☐

**Category IX: Stroke**

Stroke ☐

**Required Submissions:**

In order to enroll in the Settlement Program and submit a claim for an Enhancement, you must submit the following documents with your Claim Form:

- ☐ Manufacturer/product stickers identifying the devices and hardware implanted during each surgery for which you are claiming an Enhancement.
- ☐ Operative reports, if applicable, and other records or notes for each surgery for which you are claiming eligibility that show you are entitled to your claimed Enhancement(s). By way of example, such other records or notes might include for each claimed Enhancement:
  - (a) admission histories, emergency room records (if applicable), pathology reports, radiology or imaging reports, and discharge summaries;
  - (b) contemporaneous progress notes, lab results, and/or radiology/imaging/diagnostic reports from the treating orthopedic surgeon(s) relating to the hip(s) at issue for the time period from the implantation surgery to each event and/or surgery for which you are claiming an Enhancement;

(c) contemporaneous progress notes, lab results, and/or radiology/imaging/diagnostic reports from any other treating physician (e.g. cardiologist, infections disease specialist, cardiothoracic surgeon, pulmonologist, neurologist) from the time period from the implantation surgery to each event and/or surgery for which you are claiming an Enhancement.

#### **Section G: Income Loss**

This section is for a Claimant who is claiming an income loss related to a Qualified Revision Surgery. In order to be eligible for this Enhancement, the Claimant must demonstrate an actual economic loss. As a result, this Enhancement is not available to a Claimant who was not employed and/or retired at the time of his/her Qualified Revision Surgery. The maximum award for Income Loss under the Settlement Agreement is \$10,000 (CAD). If the Claimant is claiming an income loss of more than \$10,000 (CAD), s/he will be limited to the maximum amount of \$10,000 (CAD) (if applicable and if deemed eligible for this Enhancement). In addition, the income loss Enhancement is subject to an aggregate cap of \$65,000 (CAD) for qualifying Unilateral Revision Claimants and \$80,000 (CAD) for qualifying Bilateral Revision Claimants as set forth in Section F above. **Medically Precluded Claimants are not entitled to an Income Loss Enhancement under the Settlement Program.**

Is the Claimant asserting a claim for Income Loss under the Settlement?

☐ Yes ☐ No

If you checked "No," please skip to Section K. If you checked "Yes," please complete this section.

Please briefly explain the basis for your Income Loss claim:

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#### **Required Submissions**

In order to enroll in the Settlement Program and submit a claim for Lost Income, you must submit the following documents with your Claim Form:

- ☐ Income Tax Statements, T4s, Notices of Assessment or other statements that evidence the Claimant's income from employment or self-employment from two years preceding the Implant Surgery to present.
- ☐ Supporting Employment records from two years preceding the Implant Surgery to the present.

#### Section H: Out-of-Pocket Expenses

This section is for a Claimant who has undergone a Qualified Revision Surgery(ies) and has incurred out-of-pocket expenses associated with that Qualified Revision Surgery(ies). Under the Settlement Agreement, such Claimant may receive a **single award of up to \$2,500 (CAD)** for out-of-pocket expenses related to the Qualified Revision Surgery(ies), regardless of whether the Claimant is a qualifying Bilateral Revision Surgery Claimant. All claims under this Section H must be supported by documentary proof. A Claimant who is claiming more than \$2,500 (CAD) in out-of-pocket expenses will be limited to a maximum of \$2,500 (CAD) (if applicable and if deemed eligible for this Enhancement). **Medically Precluded Claimants are not entitled to claim out-of-pocket expenses under the Settlement Program.**

Did the Claimant incur any out-of-pocket expenses in connection with a Revision Surgery, post-revision complications, or medical treatment?

☐ Yes ☐ No

If you checked "No," skip to Section I. If you checked "Yes," please answer the following:

Are these claimed out-of-pocket expenses \$2,500 (CAD) or less?

☐ Yes ☐ No

If you checked "Yes" above, you are entitled to recover no more than \$2,500 (CAD) in out-of-pocket expenses. Do you have receipts to substantiate the expenses you incurred?

☐ Yes ☐ No

#### Required Submissions

If "Yes," please attach your receipts to this form. If "No," please state the approximate total of the expenses you incurred: \$\_\_\_\_\_.

For all Claimants who are making a claim for out-of-pocket expenses, please provide a description of expenses incurred below.

Expenses:

Amount:

**Section I: Claimant's Principal Caregiver Information (if applicable)**

This section is for a Principal Caregiver who provided care for an enrolled Claimant who underwent a Qualified Revision Surgery. Only a family member may qualify as a Principal Caregiver. Under the Settlement, a Principal Caregiver may be entitled to receive a single award of up to \$5,000 (CAD), regardless of the number of caregivers or whether the Claimant is a qualifying Bilateral Revision Surgery Claimant. Note that family members of Medically Precluded Claimants are not entitled to claim a Principal Caregiver award.

Did a family member provide the Claimant with care to assist in the Claimant's recovery after his/her Qualified Revision Surgery(ies) to remove the Rejuvenate Modular?

☐ Yes ☐ No

If you checked "No," please skip to Section K. If you checked "Yes," list the family member's name and his/her relationship to the Claimant:

Name of Family Member

Relationship to Claimant

**Please Note: If a family member is making a claim as a Principal Caregiver, that family member must also complete the attached Principal Caregiver Declaration under Section L below and include it with this form.**

**Section J: Medically Precluded Claimant (if applicable)**

This section is only for a Claimant who qualifies as a Medically Precluded Claimant. A Medically Precluded Claimant is a Claimant for whom, as of May 2, 2019, a Revision Surgery of his/her Rejuvenate Modular has been recommended, but s/he is unable to undergo a Revision Surgery due to the existence of a documented medical condition. The need, and reason, for the Revision Surgery, and the determination of an inability to undergo the Revision Surgery due to the existence of a documented medical condition, must be established by medical records made at the time of the respective determinations. Please note that age is not a medical condition. If the Claimant is not a Medically Precluded Claimant, please skip to Section K below. Please note that if the Claimant is unrevised but is not a Medically Precluded Claimant, s/he is not eligible for the Settlement Program.



Has the Claimant's doctor recommended Revision Surgery prior to May 2, 2019, but also advised the Claimant that he or she is unable to undergo a Revision Surgery due to the existence of a documented medical condition?

☐ Yes ☐ No

Please identify the name and address of the doctor who advised the Claimant, the date of discussion, and the medical condition(s) that prevents the Claimant from having a Revision Surgery.

Doctor:

Address:

Approximate Date(s) of Discussion (MM/DD/YYYY):

Medical condition(s):

<b>Required Submissions</b>
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In order to enroll in the Settlement Program and submit a claim as a Medically Precluded Claimant, you must submit the following documents with your Claim Form in addition to the applicable Required Submissions identified in Section D:

- ☐ Copies of specific Contemporaneous Medical Records created prior to May 2, 2019 that support the Claimant's claim that a Revision Surgery is recommended by his/her treating orthopaedic surgeon due.
- ☐ Copies of specific Contemporaneous Medical Records created prior to May 2, 2019 by the treating physician or consulting medical specialist that support the Claimant's claim that s/he is too infirm to undergo a Revision Surgery.

<b>Section K: Declaration</b>
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I solemnly declare that:

The Claimant was implanted with a Rejuvenate Modular.

The Claimant wishes to make a claim for compensation in this Settlement.

Attached are copies of the Claimant's implant and revision (if applicable) operative reports and documentation identifying the catalogue and lot numbers of the Claimant's Rejuvenate Modular.

I have also attached copies of all other Contemporaneous Medical Records and other documents upon which the Claimant relies in support of his/her claim.

I declare the statements in this form to be true, and knowing that it is of the same legal force and effect as if it were made under oath.

Signature of Claimant or Representative

Date

**Please Note: All pages of this form and all supporting documents must be submitted to the Claims Administrator on or before the applicable Claims Period Deadline.**

**Section L Principal Caregiver Declaration (if applicable)**

**Please Note:** This form must be completed if a family member is making a claim as a Principal Caregiver.

First Name Middle Last Name

Address

City Province/Territory Postal Code

Daytime Phone Number Cellular Phone Number

Email

Name of Claimant

Relationship to Claimant

Did you provide primary care to a Claimant?

☐ Yes ☐ No

If you checked "Yes," please state the nature of the care you provided. Please provide approximate dates and sufficient detail to allow for an understanding of the care provided and the impact upon you.

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Did you incur personal expenses in order to provide care to the Claimant?

☐ Yes ☐ No

If you checked "Yes," please attach your receipts for expenses to this form. If you checked "No," please state the approximate total of the expenses you incurred: \$ \_\_\_\_\_. Please provide a description of expenses incurred below.

Expenses

Amount


I declare the statements in this form to be true, and knowing that it is of the same legal force and effect as if it were made under oath.

\_\_\_\_\_  
Signature of Principal Caregiver

\_\_\_\_\_  
Date

**SCHEDULE B**

**PROPOSED COURT ORDER ON  
NOTICE OF HEARING FOR SETTLEMENT APPROVAL**

Court File No. CV-14-504302-00CP

THE HONOURABLE ) DAY, THE  
JUSTICE BELOBABA ) DAY OF , 2019

BETWEEN:

ROSEMARY RITLOP and DONILDA LACKNER

Plaintiffs

- and -

STRYKER CANADA LP, STRYKER CANADA CORP., STRYKER  
CANADIAN MANAGEMENT INC., HOWMEDICA OSTEONICS  
CORPORATION c.o.b. as STRYKER ORTHOPEDICS and  
STRYKER CORPORATION

Defendants

Proceeding under the *Class Proceedings Act*, 1992

**ORDER**

**THIS MOTION** by the Representative Plaintiffs for an order approving the form of notice that will advise class members of the hearing to approve the proposed settlement, as well as the manner of publicizing such notice, was heard in Toronto.

**UPON BEING ADVISED** that the Representative Plaintiffs and the Defendants have entered into the Settlement Agreement attached hereto as Schedule "A" and that the Defendants have consented to the terms of this Order;

1. **THIS COURT ORDERS** that for the purposes of this Order, the definitions set out in the Settlement Agreement apply to and are incorporated into this Order.
2. **THIS COURT ORDERS** that the motion for approval of settlement in this proceeding shall be heard on [●] at 361 University Ave, Toronto, Ontario (the "Approval Hearing").
3. **THIS COURT ORDERS** that the form and content of the hearing notice, substantially in the form attached hereto as Schedule "B", is approved (the "Hearing Notice"). The Hearing Notice shall be available in both English and French.
4. **THIS COURT ORDERS** that
  - (a) Class Counsel shall send a copy of the Explanation Letter and the Notice of the Settlement Approval Hearing Attached as Schedule "A" to all Class Members who have contacted Class Counsel regarding the action and provided their contact information;
  - (b) Class Counsel shall post a copy of the Notice of the Settlement Approval Hearing to its websites; and
  - (c) Class Counsel and the Defendants will mail or email a copy of the Notice of the Settlement Approval Hearing to any lawyer who they know represents a person claiming to have been implanted with a Stryker Rejuvenate Modular Hip System or any other person they know claiming to have been implanted with a Stryker Rejuvenate Modular Hip System.
5. **THIS COURT ORDERS** that service of the Motion Record for Notice Approval dated [●] on the Hospitals, as defined in the Certification Order, by regular mail, be and the same is hereby deemed effective as of [●].
6. **THIS COURT ORDERS** that each Hospital shall, within 30 days of receipt of this order, check the healthcare number in the provincial healthcare system for each person implanted at that Hospital with a Stryker Rejuvenate Modular Hip System to confirm each person's current address and provide it to Epiq Class Action Services Canada Inc. ("Epiq").
7. **THIS COURT ORDERS** that within 10 days of receipt, Epiq shall mail a copy of the Explanation Letter and the Notice of the Settlement Approval Hearing to the address that the Hospital has for each person implanted at that Hospital.

8. **THIS COURT ORDERS** for each Explanation Letter and the Notice of the Settlement Approval Hearing that were returned by Canada Post ("Returned Notices"), Epiq will perform additional searches for such Class Members using Whitepages.ca, 411.ca, reverse address checks and other search engine checks it deems appropriate.
9. **THIS COURT ORDERS** that within 1 week of being provided with the Returned Notices in accordance with Paragraph 6, if Epiq locates new and/or different addresses for the Class Members that were sent Returned Notices, Epiq shall send the Explanation Letter and the Notice of the Settlement Approval Hearing to these new and/or different addresses (the "Additional Notices").
10. **THIS COURT ORDERS** that Epiq provide Class Counsel and the Defendants with a report of which Hospitals responded, the number of persons to whom Epiq sent the notice, the number of reported Returned Notices and the number of Additional Notices provided by Epiq, and the identities of any Hospitals, if any, that did not respond, within 68 days from the date of this Order; such report shall be kept confidential and is not to be filed with the Court, absent further order or a written direction jointly signed by lawyers for both the Class and the Defendants.
11. **THIS COURT ORDERS** that Epiq keep the names and addresses confidential, except as otherwise ordered by this Court.
12. **THIS COURT ORDERS** that the Hearing Notice and the Notice Plan constitute fair and reasonable notice to the class of the Approval Hearing.

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Registrar

SCHEDULE C

PROPOSED COURT ORDER ON  
APPROVAL OF SETTLEMENT AGREEMENT

Court File No. CV-14-504302-00CP

ONTARIO  
SUPERIOR COURT OF JUSTICE

THE HONOURABLE ) DAY, THE  
JUSTICE BELOBABA ) DAY OF , 2019

BETWEEN:

ROSEMARY RITLOP and DONILDA LACKNER

Plaintiffs

- and -

STRYKER CANADA LP, STRYKER CANADA CORP., STRYKER  
CANADIAN MANAGEMENT INC., HOWMEDICA OSTEONICS  
CORPORATION c.o.b. as STRYKER ORTHOPEDICS and STRYKER  
CORPORATION

Defendants

Proceeding under the *Class Proceedings Act, 1992*

ORDER

THIS MOTION, made by the representative Plaintiffs for approval of the settlement of this action pursuant to s. 29 of the *Class Proceedings Act, 1992*, in accordance with the terms of the Settlement Agreement was heard this day in Toronto.

UPON READING the Representative Plaintiffs' motion record, and upon hearing the submissions of counsel for the representative Plaintiff and counsel for the Defendants, fair and



adequate notice of the within hearing having been provided to Class Members in accordance with the Notice Approval Order of this Court dated [●];

**THIS COURT ORDERS AND DECLARES that:**

1. The definitions set out in the Settlement Agreement, which is attached hereto as Schedule "A", apply to and are incorporated into this Order.
2. The settlement of this action, as set out in the Settlement Agreement, is fair, reasonable, and in the best interests of the Class Members, and is hereby approved pursuant to s. 29 of the *Class Proceedings Act, 1992* and shall be implemented in accordance with its terms.
3. The Settlement Agreement and this Order are binding upon the Representative Plaintiffs and each Class Member, whether or not such person receives or claims compensation, including persons who are minor or are mentally incapable.
4. The Defendants shall pay the amounts required under the Settlement Agreement, subject to the Right of Termination set out in Section 8 of the Settlement Agreement.
5. The form and content of the Notice of Approval of Settlement shall be substantially in the form which appears at Schedule E to the Settlement Agreement.
6. Class Members shall be given notice of this order in accordance with the plan attached as Schedule F to the Settlement Agreement. The notice shall be available in both English and French.
7. The notification plan described in Schedule F to the Settlement Agreement satisfies the requirements of s. 17 of the *Class Proceedings Act*.
8. Epiq Class Action Services Canada Inc. is hereby appointed as Claims Administrator.
9. Upon the Effective Date, the Released Persons are forever and absolutely released by the Releasing Persons from the Released Claims including, but not limited to all claims, actions, causes of action, suits, debts, duties, accounts, bonds, covenants, contracts, and demands whatsoever that were asserted, or could have been asserted, and that are the subject of this Settlement Agreement. The Releasing Persons are barred from taking or continuing any

proceedings arising out of or relating to the Released Claims against any other person, corporation, or entity (including, without limitation, any health care professionals, health care providers, or health care facilities) that might claim damages and/or contribution and indemnity and/or other relief under the provisions of the *Negligence Act* or other comparable provincial legislation and any amendments thereto, the common law, Quebec civil law, or any other statute, for any relief whatsoever, including relief of a monetary, declaratory, or injunctive nature, from one or more of the Released Persons.

10. The Releasing Persons shall not now or hereafter institute, continue, maintain, or assert, either directly or indirectly, whether in Canada or elsewhere, on their own behalf or on behalf of, or as part of, any class or any other person, any action, suit, cause of action, claim, or demand relating to the Released Claims against any Released Persons. No Class Members shall recover, directly, indirectly, or derivatively any sum from Defendants or Released Persons other than the sum authorized under the Settlement Agreement in connection with the Affected Product.

11. Neither the Settlement Agreement (including all terms thereof) nor performance under the terms of the Settlement Agreement by the Defendants is, or shall be, construed as any admission by the Defendants, including but not limited as to: (1) the validity of any claim, theory, or fact; (2) any liability, fault, or responsibility; or (3) the existence, cause, or extent of any damages or losses alleged or suffered by the Representative Plaintiff or any Class Member.

12. This Court shall have continuing jurisdiction over the implementation and enforcement of the Settlement Agreement.

13. This action is hereby dismissed without costs and with prejudice.

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Justice Belobaba

**SCHEDULE D**

**PROPOSED EXPLANATION LETTER AND  
FORM OF NOTICE OF SETTLEMENT APPROVAL HEARING**

[class counsel letterhead]

**NOTICE OF STRYKER HIP IMPLANT SETTLEMENT APPROVAL HEARING**

Dear Sir/Madam,

**Re: Your Stryker Rejuvenate Modular Hip Implant**

We are the court-approved lawyers for all class members in a national class action lawsuit which was certified by the Court for people who were implanted with a Stryker Rejuvenate Modular Hip System in Canada.

The Ontario Superior Court has ordered this letter and the enclosed notice be mailed by health care institutions to people who have been implanted with a Stryker Rejuvenate Modular Hip System.

We are writing to you because there is a proposed settlement of the lawsuit on behalf of people who were implanted with a Stryker Rejuvenate Modular Hip System in Canada. You have been identified by hospital records as an individual who has been implanted with a Stryker Rejuvenate Modular Hip System, and you have not opted out of the certified Class Action.

**The enclosed notice may affect your rights. Please read it carefully. Your name and private information have not been disclosed to us. Unless you contact us to provide your information, we will not be able to contact you directly.**

We encourage you to review the enclosed Notice carefully. Should you have any questions at this time, we invite you to access the website [●] or to contact Class Counsel using the contact information in the enclosed Notice.

**Were you implanted with a Rejuvenate Modular Hip System® in Canada?**

**This notice may affect your rights. Please read carefully.**

A class action lawsuit was started in Canada about the Stryker Rejuvenate Modular Hip System, alleging it was defective, and that it failed prematurely. Specifically, a class action was certified by the Ontario Superior Court in Toronto on December 8, 2015 in *Ritlop v. Stryker Canada et al.* Please note that this Notice does relate to any other Stryker hip implant system, including the Rejuvenate Monoblock Hip System.

The Defendants, while not admitting liability, have agreed to a settlement of this lawsuit. For a copy of the settlement agreement, which sets out how much compensation you might be entitled to, or for more information, please contact Class Counsel listed below.

**Who is Eligible to Participate in the Settlement?**

The settlement applies to all persons who were implanted with a Stryker Rejuvenate Modular Hip System in Canada who have not opted out of the class action and their estates and family members.

**The Terms of the Settlement**

The settlement provides compensation to class members who timely submit all forms and documentation required under the Settlement Agreement. The settlement also provides for payment to public health insurers. Please refer to the settlement agreement for specific terms and conditions.

**Court Hearings and Your Right to Participate**

A motion to approve the settlement agreement is scheduled to be heard by the Ontario Superior Court in Toronto on [●]. Class Counsel will also ask the courts to approve an award of fees and disbursements in the amount of [\$●] for their work in connection with this Class Action.

All class members have the right to present arguments to the Ontario Court as regards the settlement, or to object to the settlement or Class Counsel fees, by delivering a written submission to Class Counsel on or before [●]. A class member who wishes to object to the settlement shall provide in his or her objection:

- (a) The full name, current mailing address, fax number, telephone number, and email address of the person who is objecting;
- (b) A brief statement of the nature and reasons for the objection or, if you want the settlement to proceed, that you support for the settlement;
- (c) A declaration that the person believes he or she is a member of the Class and the reason for that belief including, if available, the catalogue and lot numbers of his/her Rejuvenate Modular Hip System;

- (d) Whether the person intends to appear at the relevant Approval Hearing or intends to appear by counsel, and if by counsel, the name, address, telephone number, fax number, and email address of counsel; and
- (e) A declaration under the penalty of perjury that the foregoing information is true and correct.

**Class members who do not oppose the settlement need not appear at the hearings or take any other action at this time to indicate their desire to participate in the settlement.**

**For Additional Information and a Copy of the Settlement Agreement Please Contact:**

**Koskie Minsky LLP**  
20 Queen Street West, Suite  
900, Box 52  
Toronto, ON M5H 3R3  
Telephone: 416.977.8353  
Facsimile: 416.977.3316  
[www.kmlaw.ca](http://www.kmlaw.ca)

**Klein Lawyers**  
100 King Street West, Suite  
5600  
Toronto, ON M5X 1C9  
Telephone: 416.506.1944  
Facsimile: 416.506.0601  
[www.callkleinlawyers.com](http://www.callkleinlawyers.com)

**Stevenson Whelton LLP**  
Barristers & Solicitors  
15 Toronto Street, Suite 200  
Toronto, ON M5C 2E3  
Telephone: 416.599.7900  
Facsimile: 416.599.7910  
[www.swlawyers.ca](http://www.swlawyers.ca)

We also encourage you to visit the class action website [●] after [●] to obtain additional information regarding the status of the settlement approval. If settlement approval is granted by the Ontario Court additional information regarding how to participate in the settlement will be posted on the website.

Any questions about the matters in this Notice should not be directed to the Court, because its administrative structure is not designed to address this type of inquiry.

## **SCHEDULE E**

### **FORM OF NOTICE OF SETTLEMENT APPROVAL**

#### **STRYKER HIP IMPLANT CLASS ACTION SETTLEMENT**

**Were you implanted with a Rejuvenate Modular Hip System® in Canada? You may be eligible for compensation.**

**This notice may affect your rights. Please read carefully.**

A class action lawsuit was initiated in Canada regarding allegations that the Stryker Rejuvenate Modular Hip System was defective, and that it failed prematurely. Specifically, a class action was certified by the Ontario Court on December 8, 2015 in *Ritlop v. Stryker Canada et al.* Please note that this Notice does relate to any other Stryker hip implant system, including the Rejuvenate Monoblock Hip System.

These actions have now been settled, and the Ontario Court has approved the settlement. For a copy of the settlement agreement, please contact Class Counsel or the Claims Administrator at the address below.

#### **Who is Eligible to Participate in the Settlement?**

The settlement applies to all persons who were implanted with a Stryker Rejuvenate Modular Hip System in Canada who have not opted out of the class action and their estates and family members.

#### **The Terms of the Settlement**

The settlement provides compensation to class members who timely submit all forms and documentation required under the Settlement Agreement. The settlement also provides for payment to public health insurers. Please refer to the settlement agreement for specific terms and conditions.

#### **To Make a Claim**

To be entitled to a payment pursuant to the settlement agreement, class members must file a claim with the Claims Administrator on or before their applicable claims period.

**For More Information or to Obtain a Claim Form**

Please contact Class Counsel or the Claims Administrator at the address below:

**Koskie Minsky LLP**  
20 Queen Street West, Suite  
900, Box 52  
Toronto, ON M5H 3R3  
Telephone: 416.977.8353  
Facsimile: 416.977.3316  
www.kmlaw.ca

**Klein Lawyers**  
100 King Street West, Suite  
5600  
Toronto, ON M5X 1C9  
Telephone: 416.506.1944  
Facsimile: 416.506.0601  
www.callkleinlawyers.com

**Stevenson Whelton LLP**  
Barristers & Solicitors  
15 Toronto Street, Suite 200  
Toronto, ON M5C 2E3  
Telephone: 416.599.7900  
Facsimile: 416.599.7910  
www.swlawyers.ca

Claims Administrator:

Epiq Class Action Services Canada Inc.  
[●]

We also strongly encourage you to visit the class action website [●] to obtain additional information regarding the settlement. Additional information regarding how to participate in the settlement is posted on the website.

Any questions about the matters in this Notice should not be directed to the Court, because its administrative structure is not designed to address this type of inquiry.

**SCHEDULE F**  
**PLAN FOR DISSEMINATION OF**  
**NOTICE OF APPROVAL HEARING AND**  
**NOTICE OF THE ORDER APPROVING THE SETTLEMENT**

The **Notice of Approval Hearing** shall be disseminated by the following means:

1. Class Counsel shall send a copy of the Explanation Letter and the Notice of Approval Hearing by mail or email to all class members who have contacted them, and those Class Members who have provided addresses to Class Counsel for the purposes of this action.
2. Class Counsel shall post a copy of the Notices of Approval Hearing and the Settlement Agreement to the website [●].
3. Class Counsel and the Defendants will mail or email a copy of the Notice of Settlement Approval Hearing to any lawyer who they know represents a person claiming to have been implanted with a Stryker Rejuvenate Modular Hip System or any other person they know claiming to have been implanted with a Stryker Rejuvenate Modular Hip System.
4. The Notices of Approval Hearing and Settlement Approval shall be distributed by Epiq Class Action Services Canada Inc. ("Epiq"). The Parties shall seek an order from the Ontario Court in the form set forth in Schedule B of the Settlement Agreement that directs the Hospitals who distributed the Notice of Certification by order dated March 3, 2016 to provide Epiq with Class Member information to facilitate Epiq's distribution of the Notices of Approval Hearing and Settlement Approval to Class Members.

The **Notice of the Order Approving the Settlement** shall be disseminated by the following means:



1. Class Counsel shall send a copy of the Explanation Letter and the Notice of the Order Approving the Settlement to all class members who have contacted Class Counsel regarding the action and provided their contact information.
2. Class Counsel shall post a copy of the Notice of the Order Approving the Settlement to the website [●].
3. Class Counsel and the Defendants will mail or email a copy of the Notice of the Settlement Approval Hearing to any lawyer who they know represents a person claiming to have been implanted with a Stryker Rejuvenate Modular Hip System or any other person they know claiming to have been implanted with a Stryker Rejuvenate Modular Hip System.
4. The Notices of Approval Hearing and Settlement Approval shall be distributed by Epiq to the individuals identified by the Hospitals in accordance with the Notice of Approval Hearing, subject to any updates to their mailing addresses previously made by Epiq.

**SCHEDULE G**

**PROPOSED COURT ORDER REGARDING  
DISTRIBUTION OF NOTICES OF SETTLEMENT APPROVAL**

Court File No. CV-14-504302-00CP

**ONTARIO  
SUPERIOR COURT OF JUSTICE**

THE HONOURABLE ) DAY, THE  
JUSTICE BELOBABA ) DAY OF , 2019

BETWEEN:

ROSEMARY RITLOP and DONILDA LACKNER

Plaintiffs

- and -

STRYKER CANADA LP, STRYKER CANADA CORP., STRYKER  
CANADIAN MANAGEMENT INC., HOWMEDICA OSTEONICS  
CORPORATION c.o.b. as STRYKER ORTHOPEDICS and STRYKER  
CORPORATION

Defendants

*Proceeding under the Class Proceedings Act, 1992*

1. **THIS COURT ORDERS** that the definitions set out in the Settlement Agreement apply to and are incorporated into this Order.

2. **THIS COURT ORDERS** that:

- (a) Class Counsel shall send a copy of the Explanation Letter and the Notice of Settlement Approval attached as Schedule "A" to all class members who have

contacted Class Counsel regarding the action and provided their contact information;

(b) Class Counsel shall post a copy of the Notice of Settlement Approval to its websites; and

(c) Class Counsel and the Defendants will mail or email a copy of the Notice of Settlement Approval to any lawyer who they know represents a person claiming to have been implanted with a Stryker Rejuvenate Modular Hip System or any other person they know claiming to have been implanted with a Stryker Rejuvenate Modular Hip System.

3. **THIS COURT ORDERS** that within 30 days of the Final Approval Date, Epiq Class Action Services Canada Inc. ("Epiq") shall mail a copy of the Explanation Letter and the Notice of Settlement Approval to the addresses provided by the Hospitals pursuant to the order providing Notice of the Settlement Approval Hearing dated [●], subject to any updates to the addresses conducted by Epiq.

4. **THIS COURT ORDERS** that the Notice and the Notice Plan constitute fair and reasonable notice to the Class of Settlement Approval.

## SCHEDULE H

### LIST OF ENHANCEMENTS AND CORRESPONDING DEFINITIONS AND PAYMENT AMOUNTS UNDER THE ENHANCEMENTS BENEFIT PROGRAM

In addition to the definitions set forth in the Settlement Agreement, the following applies for any Enhancements set forth in this Schedule:

#### SECTION 1: DEFINITIONS

1) "Additional Surgery" means the following separate and specific procedures following a Qualified Revision Surgery: Removal of Hardware; Debridement and/or Removal of Pseudotumors; Surgical Repair/Reattachment of a Damaged Abductor Muscle Complex; Placement of Constrained Component Due to Dislocation; and/or Post-Revision Femur Fracture. An Approved Claimant shall receive only one (1) Additional Surgery Enhancement per qualifying Additional Surgery, regardless of the number of Additional Surgery Enhancements that may apply to a single surgical procedure. An Approved Claimant who undergoes a surgical procedure that would qualify as an Additional Surgery, Dislocation, and/or an Infection-Related Open Surgical Procedure may only receive one (1) Enhancement for that surgery, the greater of which applies. If, however, an Approved Claimant undergoes a surgical procedure that would also qualify as a Re-Revision Surgery, s/he shall only receive a Re-Revision Surgery Enhancement for that surgical procedure.

2) "Blood Clot" means a diagnosis made within 72 hours of a Qualified Revision Surgery or Covered Open Surgical Procedure under General Anesthesia of a pulmonary embolism (an obstruction of an artery in the lungs caused by a blood clot) or deep vein thrombosis (a condition in which a blood clot forms in one or more of the veins in the legs or pelvis) requiring further hospitalization. An Approved Claimant is entitled to only one Blood Clot Enhancement per Qualified Revision Surgery or Covered Open Surgical Procedure Under General Anesthesia.

3) "Closed Reduction" means a Dislocation that was managed with a closed reduction at a hospital.

4) "Covered Open Surgical Procedure Under General Anesthesia" means a Re-Revision Surgery, Additional Surgery, Open Reduction, Open Reduction with Conversion to a Constrained Component, or Infection-Related Open Surgical Procedure as set forth in each herein.

5) "Death" means an Approved Claimant who died (i) during the Qualified Revision Surgery or Covered Open Surgical Procedure under General Anesthesia, or (ii) during the hospitalization for the Qualified Revision Surgery or Covered Open Surgical Procedure Under General Anesthesia.

6) "Debridement and/or Removal of Pseudotumors" means an Additional Surgery following a Qualified Revision Surgery or Re-Revision Surgery that required debridement and is

preceded by objective documented evidence through preoperative imaging, or supported by intra-operative findings or pathology that demonstrates the presence of tissue damage related to the reasons underlying the Voluntary Recall. This Additional Surgery Enhancement excludes exploratory surgeries, the debridement of scar tissue, and the debridement of hematomas and/or seromas.

7) “Dislocation” means the dislocation of the femoral head of the hip in which the Affected Product was removed following a Qualified Revision Surgery or Re-Revision Surgery provided that (i) the first dislocation occurred within nine (9) months after a Qualified Revision Surgery or Re-Revision Surgery, whichever is later; (ii) the dislocation event is documented by a diagnosis in Contemporaneous Medical/Hospital Records; and (iii) the dislocation event necessitated (a) a Closed Reduction in a hospital, or (b) an Open Reduction in a hospital. Excluded from this Enhancement are: (i) Dislocations that occur before the Index Surgery and/or before the Qualified Revision Surgery; (ii) Dislocations that are caused or precipitated by Trauma as defined in Section 1.2.34; and/or (iii) Dislocations of an articulating antibiotic spacer that was placed during a Qualified Revision Surgery that is also the first stage of a two-stage Infection-Related Open Surgical Procedure, and prior to the placement of a permanent femoral component. An Approved Claimant who undergoes a surgical procedure that would qualify as a Dislocation, an Additional Surgery, and/or an Infection-Related Open Surgical Procedure may only receive one (1) Enhancement for that surgical procedure, the greater of which applies.

8) “Events Associated with Qualified Revision Surgery or Re-Revision Surgery” means complications specifically set forth below in Category III that took place during a Qualified Revision Surgery or Re-Revision Surgery.

9) “Foot Drop” means an injury to the peroneal nerve as a result of a Qualified Revision Surgery or Re-Revision Surgery in the hip in which the Affected Product was removed that resulted in the inability to lift the front part of the foot and which is diagnosed during the hospitalization for the Qualified Revision Surgery or Re-Revision Surgery and existing more than ninety (90) days after the date of the Qualified Revision Surgery or Re-Revision Surgery. Excluded from this Enhancement are foot drops that occur before the Index Surgery and/or before the Qualified Revision Surgery.

10) “Infection” means an infection (as defined in Section 1.2.33) of the hip in which the Affected Product was removed that is diagnosed within nine (9) months of a Qualified Revision Surgery, Re-Revision Surgery, or Additional Surgery and does not form the basis for an Excluded Infection-Related Revision Surgery.

11) “Infection-Related Non-Surgical Treatment” means non-surgical treatment of an Infection in the hip in which the Affected Product was removed that occurs within ninety (90) days of the diagnosis of the subject Infection and requires: (i) intravenous antibiotic treatment lasting six (6) weeks or longer; (ii) placement and continuous use of a wound vac; or (iii) treatment in a skilled nursing facility.

12) “Infection-Related Open Surgical Procedure” means a surgery under general anesthesia in the hip in which the Affected Product was removed that occurs within ninety (90)

days of the diagnosis of the subject Infection and requires either (i) irrigation and debridement of an infected surgical wound; or (ii) a two-stage surgery that requires removal of the femoral head, acetabular shell, and/or acetabular liner and a subsequent return to surgery to replace the previously removed components. Specifically excluded from this Enhancement is treatment for an Infection that was diagnosed or suspected prior to or at the time of a Qualified Revision Surgery. An Approved Claimant who undergoes a surgical procedure that would qualify as a Dislocation, an Additional Surgery, and/or an Infection-Related Open Surgical Procedure may only receive one (1) Enhancement for that surgery, the greater of which applies.

13) “Intra-Operative Femur Fracture with Osteotomy” means the unintentional fracturing of the femur bone during the course of a Qualified Revision Surgery or Re-Revision Surgery that required cabling or prosthetic fixation and either (i) resulted from an Osteotomy or (ii) was converted into an Osteotomy to remove the femoral component. “Cabling” or “prosthetic fixation” includes cables, wires, clamps, screws, plates, etc. and excludes bone putty, glue, chips, and/or the revision femoral component itself.

14) “Intra-Operative Femur Fracture without Osteotomy” means the unintentional fracturing of the femur bone during the course of a Qualified Revision Surgery or Re-Revision Surgery that required cabling or prosthetic fixation and did not (i) result from an Osteotomy or (ii) was not converted into an Osteotomy to remove the femoral component. “Cabling” or “prosthetic fixation” includes cables, wires, clamps, screws, plates, etc. and excludes bone putty, glue, chips, and/or the revision femoral component itself.

15) “Myocardial Infarction” means a myocardial infarction occurring (i) during a Qualified Revision Surgery or Covered Open Surgical Procedure under General Anesthesia, and (ii) during the hospitalization for a Qualified Revision Surgery or Covered Open Surgical Procedure Under General Anesthesia.

16) “Open Reduction” means a Dislocation that was managed with an open reduction at a hospital.

17) “Open Reduction with Conversion to a Constrained Component Due to Dislocation” means a Dislocation that was managed with an open reduction during which a constrained acetabular liner/insert was placed.

18) “Osteotomy” means a surgical procedure in which the surgeon intentionally cuts or saws the femur bone in order to facilitate removal of a femoral stem component; however, Osteotomies that occurred during an Index Surgery are excluded from this Enhancement.

19) “Placement of Constrained Component Due to Dislocation” means an Additional Surgery following a Qualified Revision Surgery or Re-Revision Surgery that requires the placement of a constrained acetabular liner/insert due to Dislocation. If a constrained acetabular liner/insert is placed during an Open Reduction, the Approved Claimant shall receive an Open Reduction with Conversion to a Constrained Component Enhancement.

20) “Post-Revision Femur Fracture” means an Additional Surgery following a Qualified Revision Surgery or Re-Revision Surgery to repair a femur fracture that occurred within ninety (90) days from a Qualified Revision Surgery or Re-Revision Surgery. This Enhancement specifically excludes a surgery to repair an Osteotomy created during a Qualified Revision Surgery or Re-Revision Surgery or an intraoperative femur fracture that was repaired (including with fixation) during a Qualified Revision Surgery or Re-Revision Surgery.

21) “Removal of Hardware” means an Additional Surgery following a Qualified Revision Surgery or Re-Revision Surgery during which hardware that was originally placed during a Qualified Revision Surgery or Re-Revision Surgery to repair an osteotomy or to repair an intraoperative femur fracture is removed.

22) “Re-Revision Surgery” means a (i) medically necessary surgery that (ii) required removal of the revision femoral stem component, (iii) was made necessary by the Qualified Revision Surgery, and (iv) was not necessitated by “Trauma” as defined in Section 1.2.34.

a) A “Re-Revision” surgery includes a two-stage Infection-Related Open Surgical Procedure that involves removal of the revision femoral component and a second surgery to place a permanent femoral stem. In such instances, the Approved Claimant will only receive one (1) Re-Revision Surgery Enhancement for both stages of the two-stage procedure. A patient, therefore, will not receive two Re-Revision Surgery Enhancements for each stage of a two-stage Infection-Related Open Surgical Procedure, no matter the circumstances.

b) Also excluded from this Enhancement are: (i) surgeries in which only the proximal body of a revision femoral stem is removed and replaced; (ii) surgeries in which the underlying Infection was diagnosed prior to or at the time of the Qualified Revision Surgery; and (iii) the second stage of a two-stage Infection-Related Open Surgical Procedure when the Qualified Revision Surgery is also the first stage of a two-stage Infection-Related Open Surgical Procedure.

c) In addition, an Approved Claimant who undergoes a surgical procedure that would qualify as a Re-Revision Surgery may only receive a Re-Revision Enhancement, regardless of whether that procedure would also qualify as an Additional Surgery, Dislocation, and/or an Infection-Related Open Surgical Procedure.

23) “Stroke” means a cerebrovascular incident or insult occurring within 72 hours of a Qualified Revision Surgery or Covered Open Surgical Procedure under General Anesthesia causing damage. A transient ischemic attack or “TIA” is not considered a stroke for purposes of this Enhancement.

24) “Surgical Repair/Reattachment of a Damaged Abductor Muscle Complex” means an actual repair to a damaged abductor that occurred during a Qualified Revision Surgery, Re-Revision Surgery, or Additional Surgery that is supported by (i) objective evidence of damage to

the abductor muscle complex related to the reasons underlying the Voluntary Recall that (ii) is sufficient to require actual surgical repair of the damaged abductor muscles that is beyond debridement of tissue (including necrotic and/or scar tissue), and excludes exploratory surgeries and the closure and/or suture reattachment of the abductor musculature that takes place as part of the ordinary course of surgery. The "abductor muscles" include the gluteus medius, gluteus minimus, and tensor fascia latae only.

## SECTION 2: CORRESPONDING PAYMENT AMOUNTS

2.1 The amounts payable under Section 4.2.8 of this Settlement Agreement to Class Members who have demonstrated by medical records contemporaneous to the Enhancement claimed and their Qualified Revision Surgery that they are entitled to an Enhancement as set forth below:

<b>Enhancement Category</b>	<b>Enhancement Amount</b>
<b>Category I: Dislocation</b>	
Dislocation – Closed Reduction	\$8,000
Dislocation – Open Reduction	\$20,000
Dislocation – Open Reduction with Conversion to a Constrained Component	\$28,750
<b>Category II: Blood Clot</b>	
Blood Clot	\$10,000
<b>Category III: Infection</b>	
Infection-Related Open Surgical Procedure	\$15,000
Infection-Related Non-Surgical Treatment	\$10,000
<b>Category IV: Events Associated with Qualified Revision Surgery or Re-Revision Surgery</b>	
Osteotomy	\$30,000
Intraoperative Femur Fracture with Osteotomy	\$35,000
Intraoperative Femur Fracture without Osteotomy	\$17,000
Surgical Repair/Reattachment of a Damaged Abductor Muscle Complex	\$30,000
<b>Category V: Re-Revision Surgery</b>	
Re-Revision Surgery – First Re-Revision	\$45,000
Re-Revision Surgery – Second Re-Revision	\$25,000
<b>Category VI: Additional Surgery</b>	
Additional Surgery	\$20,000
<b>Category VII: Foot Drop</b>	
Foot Drop	\$20,000
<b>Category VIII: Myocardial Infarction</b>	
Myocardial Infarction	\$40,000
<b>Category IX: Stroke</b>	
Stroke	\$40,000
<b>Category X: Related Death</b>	
Related Death	\$40,000



<b>Category XI: Income Loss</b>	
Income Loss	Up to \$10,000 with documentary proof

2.2 The amounts payable at Paragraph 2.1 of Schedule H are cumulative, but in no event shall more than \$65,000 in the aggregate be payable to an Unilateral Claimant or \$80,000 in the aggregate be payable to a Bilateral Claimant under this Schedule. Thus, regardless of the number of Enhancements an Approved Claimant has, s/he can recover only up to a total of \$65,000 (Unilateral Claimant) or \$80,000 (Bilateral Claimant), respectively for all Enhancements, which include the medical complications and Income Loss.

2.3 The events underlying any Enhancements claims, including Income Loss incurred, must have occurred on or before the applicable Claims Period Deadline and must be reflected in Contemporaneous Medical/Hospital Records and income and tax records, in order to be compensable under this Settlement Agreement.

2.4 All amounts are subject to the reductions set forth in this Settlement Agreement and this Schedule and to any applicable counsel fees. Any reductions are retained for the benefit of the Defendants.

## SCHEDULE I

### RECONSIDERATION PROTOCOL

The following procedure shall apply to applications brought by either Class Members or Defendants pursuant to Sections 4.5.8 and 4.5.9 of the Settlement Agreement for reconsideration of decisions issued by the Claims Administrator:

1. The party seeking reconsideration must submit to the Claims Administrator a written statement setting out the nature of, and the reasons for, the reconsideration (the "Reconsideration Statement"). A Reconsideration Statement must be submitted within 30 days of the date of any determination issued by the Claims Administrator that is eligible for reconsideration pursuant to Section 4.5.8 of the Settlement Agreement. If a party does not seek reconsideration during this time, the Claims Administrator's decision is final and binding.
2. Upon receipt of the Reconsideration Statement:
  - (a) If a Class Member Submits a Reconsideration Statement: The Claims Administrator shall send a copy of the Reconsideration Statement together with the applicable records submitted by the Class Member to the Defendants for review and consideration. The Defendants shall then inform the Claims Administrator of whether they agree or disagree with the Class Member's position within 30 days following receipt of the Reconsideration Statement. If the Defendants agree with the Class Member's position, the parties shall notify the Claims Administrator, and the Claims Administrator shall issue a new claim determination reflecting the parties' agreement. If the Defendants disagree with the Class Member's position, the parties shall notify the Claims Administrator and the Claims Administrator shall submit the Reconsideration Statement and related records to the Reconsideration Officer for review.
  - (b) If the Defendants Submit a Reconsideration Statement: The Claims Administrator shall send a copy of the Reconsideration Statement together with the applicable records submitted by the Class Member to the Class Member for review and consideration. The Class Member shall then inform the Claims Administrator of whether s/he agrees or disagrees with the Defendants' position within 30 days following the receipt of the Reconsideration Statement. If the Class Member agrees with the Defendants' position, the parties shall notify the Claims Administrator, and the Claims Administrator shall issue a new claim determination reflecting the parties' agreement. If the Class Member disagrees with the Defendants' position, the parties shall notify the Claims Administrator and the Claims Administrator shall submit the Reconsideration Statement at issue to the Reconsideration Officer for review.
3. The decision of the Reconsideration Officer shall be based solely on the records submitted by the Class Member at the time of enrollment, the parties' written submissions, and the prior decision of the Claims Administrator. No additional records may be submitted on Reconsideration and there will be no oral hearing on any reconsideration. The Reconsideration shall be conducted entirely in writing and the written submissions of each party shall not to exceed 2,000 characters.

4. The decision of the Reconsideration Officer shall be final and binding on the parties. There shall be no right of appeal from the decision.

The Parties agree that no legal costs or disbursements incurred by either party in connection with the reconsideration process shall be ordered to the successful party.

**SCHEDULE J**  
**VOLUNTARY RECALL NOTICE**

45 Innovation Drive  
Hamilton, ON L9H 7L8  
T: 905 690 5700 F: 905 690 5718  
Toll: 1 800 668 8324  
www.stryker.ca



## PRODUCT CORRECTION NOTICE

July 3, 2012

**Internal Reference#** RA2012-067 EXT [Regulatory Action Initiation Date: June 29, 2012]  
**Description:** Rejuvenate Modular Stems and Rejuvenate Modular Necks  
Product Number: please see attached

**Hospital:**

Dear Risk Management/Surgeon:

As communicated by a Field Safety Notice (FSN) dated April 30<sup>th</sup>, 2012, Stryker Orthopaedics had previously initiated a product field action correction (reference RA2012-067) for the products and lot ID referenced above. Please be advised that Stryker has now updated this action to a product recall. Please note, however, that the known potential hazards associated with Product Remediation RA2012-067 EXT have not changed from the previously communicated field safety notice (restated below for reference).

Issue:

Ongoing analysis of the global data following the Product Correction does not yield a significant increase in the global reported rate for Adverse Local Tissue Reaction (ALTR). However, the additional data, which includes variability in ALTR rates among sites, may potentially be predictive of an increased likelihood of this condition for both the Rejuvenate and ABG II Modular Hip Systems. Based on information received to date, a product field action to remove these products is being conducted.

Potential Hazards

1. Excessive metal debris and/or ion generation. Fretting and/or corrosion at or about the modular neck junction may lead to increased metal ion generation in the surrounding joint space.
  - Contact between metal ions and tissues and structures during an implant's service life may result in an Adverse Local Tissue Reaction (ALTR), the inflammation of associated tissues experiencing immunological response (metallosis, necrosis, and/or pain). An ALTR may result in the need for revision surgery.
  - Patients with a heightened sensitivity to these ions may experience a hypersensitivity/allergic reaction which may result in the need for revision surgery.
2. Excessive fretting debris. Fretting may lead to increased metal debris in the joint space (concentration of debris exceeds individual patient threshold) resulting in osteolysis. Osteolysis may be asymptomatic and may result in the need for revision surgery.

Note: Stryker has not received any reports of modular neck fracture associated with fretting/corrosion.

Risk Mitigation

The risk is mitigated by the removal of products from use.

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#### Follow-up

Surgeons should ensure that patients with ABG II Modular or Rejuvenate Modular Hip Systems are followed regularly and undergo clinical evaluation as per their surgeon and institutional protocol.

If a patient is experiencing pain and/or swelling involving the groin, buttock, lateral hip or thigh, the surgeon should rule out aseptic loosening or periprosthetic sepsis, common conditions following joint replacement surgery that are not related to an ALTR to metal wear debris. Once the surgeon has ruled out aseptic loosening and periprosthetic sepsis, the surgeon should evaluate the patient for an ALTR potentially related to metal wear debris. Testing includes blood work for metal ion levels (CR and CO levels over 7 ppb are commonly considered high) and either an MRI or ultrasound to look for soft tissue mass or fluid collection. If the results reveal an ALTR to metal wear debris, the surgeon should consider proceeding with a revision of the femoral component to a monolithic stem.

Our records indicate that you have received the above referenced product(s). It is Stryker's responsibility as the manufacturer to ensure that customers who may have received these affected products also receive this important communication.

#### Please assist us in meeting our regulatory obligation by:

- Immediately check your internal inventory and quarantine all affected devices. Return all affected devices to Stryker Canada by contacting our Customer Service Department at 1-800-668-8323 [please reference RA2012-067 EXT].
- Complete and return the attached Product Recall Accountability Form [by fax 905-690-5718 or by e-mail [CARAQA@stryker.com](mailto:CARAQA@stryker.com)]. Please complete this form even if you no longer have this product at your facility. This will preclude the need for Stryker to send any reminder notice.
- Circulate this Field Safety Notice internally to all interested/affected parties. Include any personnel responsible for the allocation/maintenance of equipment.
- Maintain awareness of this notice internally until all required actions have been completed within your facility.
- Inform Stryker if any of the subject devices have been distributed to other organizations. Please provide contact details so that Stryker can inform the recipients appropriately.
- Please inform Stryker of any adverse events associated with the use of the subject device.

On behalf of Stryker we thank you sincerely for your help and support in completing this action and regret any inconvenience that may be caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remain on the market and appreciate your assistance in meeting this objective.

Should you have any further questions or concerns, please do not hesitate to contact me at 1-905-690-5700 ext. 2110, or via e-mail at [CARAQA@stryker.com](mailto:CARAQA@stryker.com).

Yours truly,

A handwritten signature in black ink, appearing to read "La-Toya Whittle".

La-Toya Whittle  
Supervisor, Regulatory Affairs and Quality Assurance

45 Innovation Drive  
Hamilton, ON L9H 7L8  
T: 905 690 5700 F: 905 690 5718  
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### Reluvenate Modular Components

Catalog No.	Description
SPT070000S	REJUVENATE STRGHT PRFIT TMZF MOD STEM SIZE 7
SPT080000S	REJUVENATE STRGHT PRFIT TMZF MOD STEM SIZE 8
SPT090000S	REJUVENATE STRGHT PRFIT TMZF MOD STEM SIZE 9
SPT100000S	REJUVENATE STRGHT PRFIT TMZF MOD STEM SIZE 10
SPT110000S	REJUVENATE STRGHT PRFIT TMZF MOD STEM SIZE 11
SPT120000S	REJUVENATE STRGHT PRFIT TMZF MOD STEM SIZE 12
NLS-301600P	LRG TAP PRI MOD NCK 16DEG 30MM
NLS-300000B	LRG TAP PRI MOD NCK 0DEG 30MM
NLS-341600P	LRG TAP PRI MOD NCK 16DEG 34MM
NLS-340000B	LRG TAP PRI MOD NCK 0DEG 34MM
NLS-381600P	LRG TAP PRI MOD NCK 16DEG 38MM
NLS-380000B	LRG TAP PRI MOD NCK 0DEG 38MM
NLS-421600P	LRG TAP PRI MOD NCK 16DEG 42MM
NLS-420000B	LRG TAP PRI MOD NCK 0DEG 42MM
NLV-300800Y	LRG TAP PRI MOD NCK 8DEG 30MM
NLV-300800G	LRG TAP PRI MOD NCK 8DEG 30MM
NLV-340800Y	LRG TAP PRI MOD NCK 8DEG 34MM
NLV-340800G	LRG TAP PRI MOD NCK 8DEG 34MM
NLV-380800Y	LRG TAP PRI MOD NCK 8DEG 38MM
NLV-380800G	LRG TAP PRI MOD NCK 8DEG 38MM
NLV-420800Y	LRG TAP PRI MOD NCK 8DEG 42MM
NLV-420800G	LRG TAP PRI MOD NCK 8DEG 42MM

**ONTARIO  
SUPERIOR COURT OF JUSTICE**

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

**ORDER  
(Approval of Settlement)**

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