Boston Scientific Corporation National Settlement Agreement Compensation Protocol

1. Unless otherwise indicated or required by context, capitalized terms in this Compensation Protocol have the meanings assigned to them in the Settlement Agreement.

2. In this protocol, the following terms shall have the meanings set forth below.

   (a) "Approved Claimant" means a Settling Claimant that the Claims Administrator determines is eligible for compensation under the Compensation Protocol.

   (b) "Claim Form" means the claim form developed by the Claims Administrator in consultation with Class Counsel and approved by the Court.

   (c) "Claim Deadlines" means the Initial Claim Deadline and the Supplemental Claim Deadline.

   (d) "Implant Evidence" means the documentation that must be provided to establish proof of implantation with a BSC Transvaginal Mesh Device, namely:

      (i) product identification sticker, tag, or label from the implanted BSC Transvaginal Mesh Device;

      (ii) medical records contemporaneous to the implantation procedure for the BSC Transvaginal Mesh Device recording the product identification information (product numbers) from the product identification sticker, tag, or label;

      (iii) medical records contemporaneous to the implantation procedure for the BSC Transvaginal Mesh Device identifying the information of the model of the BSC Transvaginal Mesh Device;

      (iv) documentation from the implanting surgeon providing confirmation of the model of the BSC Transvaginal Mesh Device;

      (v) documentation from the implanting hospital purchasing department providing confirmation of the model of the BSC Transvaginal Mesh Device;

      (vi) documentation from the implanting surgeon providing confirmation that the implanted device was a BSC Transvaginal Mesh Device; or,

      (vii) documentation from the implanting hospital purchasing department providing confirmation that the implanted device was an BSC Transvaginal Mesh Device.

   (e) "Initial Claims" are injuries extant as of January 18, 2021 experienced by women in whom BSC Transvaginal Mesh Devices were implanted prior to April 1, 2016 and that are eligible for compensation under the Compensation Protocol.

   (f) "Initial Claim Deadline" means one hundred and twenty (120) days after the last day on which the Settlement Approval Notice is published.

   (g) "Initial Compensation Pool" means $18,000,000 less Class Counsel Legal Fees and Claims Administration Costs.

   (h) "Initial Payment Per Point" means the dollars allocated for each point in section 14.

   (i) "Referee" means the person, selected by Class Counsel and approved by the Courts, that will hear appeals from decisions of the Claims Administrator.

   (j) "Settling Claimant" has the meaning ascribed to it in the Settlement Agreement but also includes, where the context requires, a lawyer or other representative acting on behalf of a Settling Claimant.

   (k) "Supplemental Claim Deadline" means two years after the Initial Claim Deadline.

   (l) "Supplemental Claims" are injuries not extant as of January 18, 2021 experienced by women in whom BSC Transvaginal Mesh Devices were implanted prior to April 1, 2016 and/or injuries experienced by women in whom BSC Transvaginal Mesh Devices were implanted on or after April 1, 2016 that are eligible for compensation under the Compensation Protocol. Supplemental Claims include claimed worsening of Initial Claims.

   (m) "Future Injury and Late Implant Compensation Pool" means $3,500,000.00 CAD less any Class Counsel Legal Fees and Claims Administration Costs.

   (n) "Surgical or Treatment Evidence" means proof, by way of contemporaneous medical records, which may include contemporaneous physician or hospital records supplemented by a letter from the physician providing any needed clarification of the contents of the records, of each claimed surgical intervention or treatment which is used to claim compensation.

PART I: CLAIMS ADMINISTRATION

3. Administration of the Settlement Agreement and the submission, processing, approval, compensation and appeal of individual claims made pursuant to the Settlement Agreement shall be governed by the Compensation Protocol, which shall be implemented by the Claims Administrator, subject to the ongoing authority and supervision of the Ontario Superior Court of Justice.

4. Purpose of the Compensation Protocol

The purpose of the Compensation Protocol is to provide further guidance to the Claims Administrator to help ensure that:

(a) only Class Members who satisfy the eligibility criteria set out in this protocol will receive compensation from the Net Settlement Proceeds;

(b) similarly situated Approved Claimants will be treated as uniformly as possible; and

(c) Approved Claimants will receive timely compensation in a way that minimizes, to the extent reasonably possible, the Claims Administration Costs and other transaction costs associated with implementation and administration of the Settlement Agreement.

5. Claim Form

In addition to any other requirements in the Settlement Agreement and Compensation Protocol, in order to become an Approved Claimant, a Class Member must properly complete, execute and submit a Claim Form to the Claims Administrator by the relevant Claim Deadline.

The Claims Administrator may also develop such other forms as it deems necessary for the implementation and administration of the Settlement Agreement in accordance with the purpose of this Compensation Protocol. If developed, such forms must be properly completed by Settling Claimants.

Claims that are not properly and timely submitted to the Claims Administrator by the relevant Claim Deadline will be denied by the Claims Administrator. For greater clarity, the failure to meet the relevant Claim Deadline with the mandatory evidence will result in rejection of the claim within the relevant Compensation Pool.

6. Claim Deadlines

To make a claim for a portion of the Initial Compensation Pool, a Settling Claimant must file a Claim Form by the Initial Claim Deadline. To make a claim for a portion of the Future Injury and Late Implant Compensation Pool, a Settling Claimant must file a Claim Form by the Supplemental Claim Deadline.

7. Mandatory Evidence

In order to claim compensation, a Settling Claimant must provide Implant Evidence and, if claiming compensation for surgeries or treatment, Surgical or Treatment Evidence in a manner satisfactory to the Claims Administrator.

8. Claim Processing Guidelines

If, during claims processing, the Claims Administrator finds technical deficiencies in a Settling Claimant's Claim Form or Evidence, the Claims Administrator shall notify the Settling Claimant of the technical deficiencies and shall allow the Settling Claimant 60 days from the date of mailing to correct the deficiencies. Such notification shall be by way of letter sent via email, if available, or through first-class regular mail.

If the deficiencies are not corrected within the 60-day period, the Claims Administrator shall reject the claim and the Settling Claimant shall have no further opportunity to correct the deficiencies.

"Technical deficiencies" shall not include missing the Claim Deadline or failure to provide sufficient Evidence to support the Settling Claimant's claim. In the event that a Settling Claimant has requested but not yet received the Evidence, the Settling Claimant may submit true copies of the records requests that were made requesting the Evidence, and the failure to provide that Evidence will be deemed a "technical deficiency."

9. Provincial Health Insurer Rights of Recovery

A Provincial Health Insurer Fund shall be established for compensation of the relevant Provincial Health Insurer Rights of Recovery, which amount shall be taken from the Initial Compensation Pool and/or the Future Injury and Late Implant Compensation Pool, as follows.

For each payment of an Approved Claimant's claim, with a BSC Transvaginal Mesh Device implanted prior to April 1, 2016, the Claims Administrator shall apportion a payment of $6,306.34 to the Provincial Health Insurer Fund.

For each payment of an Approved Claimant's claim with a BSC Transvaginal Mesh Device implanted on or after April 1, 2016, the Claims Administrator shall apportion a payment of $3,153.17 to the Provincial Health Insurer Fund.

The Provincial Health Insurer Fund shall be no less than $1,891,902.00 (such that regardless of the number of Approved Claimant claims, there will be payment for a minimum of 300 claims) and no more than $2,364,877.50 (such that regardless of the number of Approved Claimant claims, there will be payment for a maximum of 375 claims).

For the purpose of calculating the number of Approved Claimant claims for the Provincial Health Insurer Fund, each Approved Claimant with a BSC Transvaginal Mesh Device implanted on or after April 1, 2016 shall be counted as half (0.5) an Approved Claimant.

The Provincial Health Insurers will be paid by jurisdiction in a manner proportionate to the number of Approved Claimants from each jurisdiction.

To the extent that an Approved Claimant has received health care services that have been paid for by more than one Provincial Health Insurer, the health care cost recovery will be divided on a proportionate basis consistent with the relevant health care costs borne by each Provincial Health Insurer.

Payments apportioned to the Provincial Health Insurers shall be aggregated by Provincial Health Insurer for payment from and in proportion to the total amount of each of the Initial Compensation Pool, the Future Injury and Late Implant Compensation Pool and, if further payments are made to Approved Claimants, the Excess Funds.

10. Settling Claimant Notification and Claim Appeals

(a) Notification

The Claims Administrator shall notify each Settling Claimant by way of a letter sent via email, if available, or through first-class regular mail as to the approval or rejection of his or her claim and the points awarded to the Settling Claimant.

(b) Appeals

Settling Claimants will be granted a 30-day period from the date notice was sent to appeal the rejection and/or classification of their claims. Appeals will be reviewed and assessed by the Referee. Appeals will be made in writing to the Referee, supported only by the documentation provided to the Claims Administrator. Following the outcome on appeal, there shall be no right of further appeal or review.

11. Payment of Funds and Stale Dating

The Claims Administrator shall select the most cost-effective method possible to make payments to the relevant Provincial Health Insurers as may be required and to each Approved Claimant provided the payment recipient is able to accept funds in that manner.

Cheques shall be issued such that they are stale-dated six months after issuance. Cheques that are not cashed and become stale-dated will be reissued in the Claims Administrator's sole discretion based on the circumstances of the case, and at the expense of the individual requesting the reissuance. In no circumstances will cheques be reissued after the passage of six (6) months from the date on which the first cheque became stale-dated. In no case will a third cheque be issued.

PART II: ALLOCATION OF NET SETTLEMENT PROCEEDS

12. Estate Representatives

Estate representatives of deceased Primary Class Members are eligible to submit a claim as a Primary Class Member.

13. Allocation of Settlement

The Net Settlement Proceeds will be allocated among the Settling Claimants in two pools. Settling Claimants with Initial Claims will claim against the Initial Compensation Pool. Settling Claimants with Supplemental Claims will claim against the Future Injury and Late Implant Compensation Pool.

14. Allocation of Points

Approved Claimants will be assigned points at the sole discretion of the Claims Administrator, subject to the right of appeal provided herein. The Claims Administrator will assign points based on the totality of the information and resources available to it, using its best judgment and expertise to fairly and reasonably adjudicate claims. In the event that an Approved Claimant meets the criteria for both qualifying treatment(s) and qualifying surgery(s), the Approved Claimant shall receive the points allocated to both levels. In the event that an Approved Claimant received more than one BSC Transvaginal Mesh Device, the Approved Claimant shall receive the points allocated to each BSC Transvaginal Mesh Device, including any points allocated for qualifying treatment(s) and qualifying surgery(s) attributable to each BSC Transvaginal Mesh Device.

BASE POINTS		
LEVEL	**DESCRIPTION**	**POINTS**
1	Device only (does not qualify in any other category). *Points allocated for Level 1 claims shall be capped at a maximum for $4,000.00 for each device implanted.	4 points
Qualifying Treatment(s) (maximum qualifying treatment points = 9)		
2a	One of the following qualifying treatments performed after implantation of a BSC Transvaginal Mesh Device and where the qualifying treatment was performed or prescribed for the purpose of treating a condition or symptom that is attributed by the treating medical provider to that Approved Claimant's complication from the implantation of a BSC Transvaginal Mesh Device:[1] A. Pain medications for treatment of pelvic pain (commencing at least 90 days after implantation of BSC Transvaginal Mesh Device, and with continuous use for a period of at least two months); B. Physical therapy of pelvic floor and/or vaginal area (commencing at least 90 days after implantation of BSC Transvaginal Mesh Device, and involving at least 4 sessions over a 60-day period); C. Anesthetic block (e.g. epidural, spinal) for treatment of pain in or originating from the pelvic area; D. Trigger point injection, local nerve block, or nerve ablation in the pelvic area; E. Botox injection(s) into the pelvic muscles; F. Revision and/or trim of BSC Transvaginal Mesh Device(s), which is performed using topical anesthesia or local anesthesia; G. Drainage of sinus tract or abscess occurring within the vicinity of the site of implantation or the insertion tract of BSC Transvaginal Mesh Device(s), and which is performed at least 30 days after the implantation of a BSC Transvaginal Mesh Device; H. 3 or more bacterial infections of the vagina or urinary tract treated with antibiotics at least 30 days after the implantation of a BSC Transvaginal Mesh Device; or I. Such other non-surgical mesh-related treatment(s) and/or new-onset mesh-related condition(s) as may be appropriate to consider under Level 2, including extraordinary injuries such as fistula, and organ (i.e. bladder or bowel) perforation.	6 points
2b	Two or more qualifying treatments Approved Claimants shall receive 1 point for each additional qualifying treatment up to a maximum of 3 points.	Add 1-3 points to 2a
Qualifying Surgery(s) (maximum qualifying surgery points = 24)		
3a	One qualifying surgery, defined as a surgical procedure performed under general anesthesia[2] or regional anesthesia[3] to: A. Remove all or a portion of BSC Transvaginal Mesh Device; B. Release the arms of a BSC Transvaginal Mesh Device; C. Excise or lyse scar tissue or scar bands at site of implant of a BSC Transvaginal Mesh Device; or	10 points

[1] Attribution of a condition or symptom to a complication from implantation of mesh and/or the treatment thereof may be established by a temporal relationship between the implantation of mesh, the condition and/or symptom, and/or the treatment.
[2] Absence of sensation and consciousness as induced by various anesthetic medications given by inhalation or IV Components of general anesthesia are analgesia, amnesia, muscle relaxation, control of vital signs, and unconsciousness.
[3] Anesthesia provided by injecting an anesthetic to block a particular group of sensory nerve fibres (e.g. spinal, epidural, or block).

	D. Explore the cause of a condition or symptom suspected by the treating medical provider(s) in the contemporaneous medical records to be caused by the implantation of a BSC Transvaginal Mesh Device, which is performed via an open or laparoscopic approach, and for which the operative records do not reflect that another cause of the condition or symptom (e.g. ovarian cyst, endometriosis) was determined as the cause during surgery. For clarification, where the operative records reflect that another cause of the condition or symptoms (e.g. ovarian cysts, endometriosis) was determined as a cause during surgery, and in addition reflect a concomitant findings that a BSC Transvaginal Mesh Device was also a cause of the condition or symptom, such surgical procedure constitutes a qualifying surgery[4]. For clarification, a diagnostic cystoscopy without further surgical intervention is not included in such procedures. *In the event that an eligible claimant is implanted with both a BSC Transvaginal Mesh Device(s) and one or more non-BSC mesh product(s) and during any qualifying surgery it is unclear which mesh product is revised or removed, or the cause of the condition or symptom being explored, the points attributed to such qualifying surgery will be reduced by 50%. For greater clarity, this consideration is applicable for each qualifying surgery.	
3b	Two qualifying surgeries.	14 points
3c	Three qualifying surgeries.	18 points
3d	Four or more qualifying surgeries Approved Claimants shall receive 2 points for each additional qualifying surgery up to a maximum of 6 points.	Add 2-6 points to 3c

(maximum qualifying treatment + qualifying surgery points = 33 points)

Age Adjustments	
Age as of date of implantation of BSC Transvaginal Mesh Device	a) 0-30 years = 6 points b) 31-40 years = 5 points c) 41-50 years = 4 points d) 51-60 years = 3 points e) 61-70 years = 2 points f) 71-80 years = 1 point g) 81 + years = 0 points
Date of Device Implantation Adjustment	
Date of Implantation of BSC Transvaginal Mesh Device on or after April 1, 2016	50%-point deduction

For greater clarity, pursuant to this Compensation Protocol points are not allocated for any reason other than as provided in this section including, without limitation, derivative claims of family members, pursuant to section 61(1) of the *Family Law Act*, RSO 1990, c F 3, or analogous provincial legislation or at common law.

[4] Where the operative report reflects that another cause of the condition or symptoms was determined during surgery and there is not a concomitant finding that a BSC Transvaginal Mesh Device was also the cause of the condition or symptoms, such surgery is not related to a BSC Transvaginal Mesh Device.

15. Payment of the Initial Compensation Pool

Approved Claimants with Initial Claims will be paid a *pro rata* share of the Initial Compensation Pool based on the points allocated to each such Approved Claimant.

If six months after the payment of the Initial Compensation Pool there are excess funds in the Initial Claims Pool as a result of cheques having become stale dated and/or such other forms of payment as may be made to Approved Claimants and which may otherwise expire without having been claimed, such excess funds shall be added to the Future Injury and Late Implant Compensation Pool.

16. Payment of the Future Injury and Late Implant Compensation Pool

Approved Claimants with Supplemental Claims shall be paid as follows:

(a) first, Approved Claimants with Supplemental Claims who also had Initial Claims shall have the points allocated for their Initial Claims subtracted from the points allocated for the Supplemental Claims, such that only the increase in points shall be considered (the "Net New Points");

(b) second, the Future Injury and Late Implant Compensation Pool is divided by the sum of the Net New Points and the points allocated to Approved Claimants with Supplemental Claims who did not have Initial Claims to produce the "Supplemental Payment Per Point."

Unless the Claims Administrator decides otherwise and the Court so approves, if the Supplemental Payment Per Point is greater than the Initial Payment Per Point, then Approved Claimants with Supplemental and Late Implant Claims shall be paid the Initial Payment Per Point. If the Supplemental Payment Per Point is lesser than or equal to the Initial Payment Per Point, then Approved Claimants with Supplemental and Late Implant Claims shall be paid the Supplemental Payment Per Point.

For greater certainty, Approved Claimants with Supplemental Claims who also had Initial Claims shall only be entitled to payment for Net New Points under this section.

The Provincial Health Insurer Fund will only be apportioned further funds in accordance with this Compensation Protocol for Approved Claimants that were not approved as Initial Claims. For greater clarity, further funds will not be apportioned to the Provincial Health Insurer Fund for Approved Claimants with Supplemental Claims who also had Initial Claims and such Supplemental Claims shall not be further counted towards the total number of Approved Claimants for the purpose of calculating the Provincial Health Insurer Fund described in section 9.

17. Excess Funds

If six months after the payment of the Future Injury and Late Implant Compensation Pool there are excess funds in the Future Injury and Late Implant Compensation Pool as a result of cheques having become stale dated and/or such other forms of payment as may be made to Approved Claimants and which may otherwise expire without having been claimed, and/or limiting of the Supplemental Payment Per Point to the Initial Payment Per Point value, such excess funds shall be dealt with as follows.

The Claims Administrator shall determine, in its sole discretion, if there are sufficient excess funds such that a payment can be made to Approved Claimants in an economically efficient manner. If so, such excess funds shall be paid to all Approved Claimants on a *pro rata* basis.

If the Claims Administrator determines that it is not efficient to make the *pro rata* payment or if there are still excess funds six months after the *pro rata* payment has been made and such payments are stale dated, then all excess funds shall be donated, *cy près* to an organization(s) to benefit women's health as approved by the Court and advised by Class Counsel, subject to any amounts payable to the Fonds d'aide aux actions collective in accordance with the applicable Regulation.