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FILED
ALAMEDA COUNTY

MAR 23 2021

CLERK OF THE SUPERIOR COURT

By *Quinto Victor* Deputy

SUPERIOR COURT OF THE STATE OF CALIFORNIA
COUNTY OF ALAMEDA

THE PEOPLE OF THE STATE OF
CALIFORNIA,

Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION,

Defendant.

Case No. **RG21092570**

FINAL JUDGMENT

Plaintiff, the People of the State of California ("Plaintiff"), has filed a Complaint for a permanent injunction and other relief in this matter pursuant to California Business and Professions Code sections 17200 *et seq.* and 17500 *et seq.* alleging that Defendant Boston Scientific Corporation ("BSC" or "Defendant"), committed violations of the aforementioned Acts. Plaintiff, by its counsel, and BSC, by its counsel, have agreed to the entry of this Final Judgment ("Judgment") by the Court without trial or adjudication of any issue of fact or law, and without finding or admission of wrongdoing or liability of any kind.

This Judgment may be signed by any judge of the Alameda Superior Court.

1 The Court having considered the pleadings and the Stipulation for Entry of Final
2 Judgment ("Stipulation") executed by Plaintiff and BSC filed herewith, and good cause
3 appearing,

4 **IT IS HEREBY ORDERED THAT:**

5 **1. PARTIES AND FINDINGS**

6 1.1. Plaintiff is the People of the State of California.

7 1.2. Defendant BSC is a Delaware Corporation.

8 1.3. This Court has jurisdiction over the subject matter of this lawsuit and over all
9 Parties, and venue is proper in this Court.

10 1.4. At all relevant times, BSC transacted business in the County of Alameda and
11 elsewhere in the State of California.

12 1.5. This Judgment is entered into pursuant to and subject to California Business and
13 Professions Code sections 17200 *et seq.* and 17500 *et seq.*

14 1.6. The terms of this Judgment shall be governed by the laws of the State of California.

15 1.7. This Judgment (or any portion thereof) shall in no way be construed to prohibit BSC
16 from making representations with respect to any of BSC's products in Labeling that are required
17 under Federal law, regulations, and policies or guidance having the force of law.

18 1.8. Nothing in this Judgment shall require BSC to:

19 (a) take any action that is prohibited by the Federal Food, Drug and Cosmetic
20 Act, 21 U.S.C. § 301 *et seq.* ("FDCA") or any regulation promulgated thereunder
21 or by the FDA; or

22 (b) fail to take any action that is required by the FDA, or by the FDCA or any
23 regulation promulgated thereunder.

24 **2. DEFINITIONS**

The following definitions shall be used in construing the Judgment:

25 2.1. "Covered Conduct" means BSC's marketing and promotional practices and
26 dissemination of information to Health Care Providers (HCPs) or consumers regarding BSC
27 Surgical Mesh products through the Effective Date of the Judgment.
28

1 2.2. “Effective Date” means the date on which a copy of the Judgment is approved by,
2 and becomes a Judgment of the Court.

3 2.3. “Health Care Provider” or “HCP” means any physician who in the course of his or
4 her practice may prescribe or implant BSC Surgical Mesh.

5 2.4. “BSC” or “Defendant” means Boston Scientific Corporation, and all of its officers,
6 directors, employees, representatives, agents, affiliates, parents, subsidiaries, operating companies,
7 assigns, and successors.

8 2.5. “Labeling” as used in this Judgment shall carry the same definition as that contained
9 in the Federal FDCA, specifically “all labels and other written, printed, or graphic matter (1) upon
10 any article or any of its containers or wrappers, or (2) accompanying such article” and as interpreted
11 by the courts and through FDA policy and guidance to encompass, among other things, “posters,
12 tags, pamphlets, circulars, booklets, brochures, instruction books, [and] direction sheets.”

13 2.6. “Marketing Materials” means any written or electronic material, or written or verbal
14 statements either publicly disseminated or made by or on behalf of BSC for the purpose of public
15 dissemination to induce a sale or purchase in the United States in the course of marketing,
16 promoting, or informing Health Care Providers, nurses, physician’s assistants, other medical
17 professionals, and consumers about BSC Surgical Mesh, including: Directions for Use (DFUs),
18 pamphlets, brochures, Frequently Asked Questions (FAQs), sales representative training materials
19 containing material or statements intended to be publicly disseminated, HCP training materials,
20 communications with HCPs, presentations (including poster presentations and abstract
21 presentations), seminars, videos, advertisements in any form of media, and websites hosted or
22 controlled by BSC.

23 2.7. “Multistate Executive Committee” means the Attorneys General and their staffs
24 representing California, Florida, Indiana, Maryland, Ohio, South Carolina, Texas, and Washington.

25 2.8. “Multistate Working Group” means the Attorneys General and their staffs
26 representing Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware,
27 District of Columbia, Florida, Georgia, Hawaii¹, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky,

28 ¹ Hawaii is being represented in this matter by its Office of Consumer Protection, an

1 Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri,
2 Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North
3 Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, South
4 Dakota, Tennessee, Texas, Utah², Vermont, Virginia, Washington, and Wisconsin.

5 2.9. "Parties" means BSC as defined in Section 2.4 and the Signatory Attorney General.

6 2.10. "Significant Complications" means complications of BSC Surgical Mesh, including
7 complications discovered subsequent to the Effective Date, which:

8 (a) are required to be included in product labeling or advertisements pursuant to
9 FDA regulations;

10 (b) can result in a "serious injury" as defined by 21 CFR § 803.3; or

11 (c) include the following complications, which may be ongoing:

- 12 i. Pain (pelvic, vaginal, groin/thigh, dyspareunia) (acute or chronic);
- 13 ii. Foreign body reaction (acute or chronic);
- 14 iii. Erosion into organs; exposure/extrusion into vagina;
- 15 iv. Dyspareunia;
- 16 v. Scarring/scar contracture;
- 17 vi. Mesh contracture;
- 18 vii. Tissue contracture;
- 19 viii. Fistula formation (acute or chronic);
- 20 ix. Inflammation (acute or chronic);
- 21 x. Vaginal shortening or stenosis, which may result in dyspareunia and/or
- 22 sexual dysfunction;
- 23

24 agency which is not part of the state Attorney General's Office, but which is statutorily
25 authorized to undertake consumer protection functions, including legal representation of the State
26 of Hawaii. For simplicity, the entire group will be referred to as the "Attorneys General," and
such designation, as it includes Hawaii, refers to the Executive Director of the State of Hawaii
Office of Consumer Protection.

27 ² With regard to Utah, the Utah Division of Consumer Protection is charged with
28 administering and enforcing the Consumer Sales Practices Act, the statute relevant to this
Judgment. References to the "States," "Parties," or "Attorneys General," with respect to Utah,
refers to the Utah Division of Consumer Protection.

- xi. Pain with intercourse that may not resolve;
- xii. Exposed mesh may cause pain or discomfort to the patient's partner during intercourse;
- xiii. Infection;
- xiv. Sexual dysfunction; including the inability to have intercourse;
- xv. De novo detrusor instability;
- xvi. Voiding dysfunction (incontinence, temporary or permanent lower urinary tract obstruction, difficulty urinating, pain with urination, overactive bladder);
- xvii. Bruising, bleeding (vaginal, hematoma formation);
- xviii. Abscess;
- xix. Dehiscence of vaginal incision;
- xx. Perforation or laceration of vessels, nerves, bladder, urethra, or bowel may occur during placement; and
- xxi. Failure to resolve a patient's stress urinary incontinence.

In addition, because BSC Surgical Mesh is a permanent implant, Significant Complications must acknowledge that:

- (a) The occurrence of one or more of these complications may require treatment or surgical intervention. In some instances, the complication may persist as a permanent condition after the surgical intervention or other treatment;
- (b) Removal of mesh or correction of mesh-related complications may involve multiple surgeries; and
- (c) Complete removal of mesh may not be possible and additional surgeries may not always fully correct the complications.

2.11. "Inherent Mesh Complications" shall include significant complications associated with the use of the mesh material that may not be eliminated with surgical technique (as opposed to non-mesh surgery).

1 2.12. "Signatory Attorney General" means the Attorney General of California, or his
2 authorized designee, who has agreed to this Judgment.

3 2.13. "Sponsor" is the organization or person who initiates a study and who has authority
4 and control over a study relating to BSC Surgical Mesh.

5 2.14. "Support" shall mean financial or product support, or as otherwise defined as
6 support in a contractual agreement with an HCP or consultant relating to BSC Surgical Mesh.

7 2.15. "State Consumer Protection Laws" means the consumer protection laws cited in
8 Footnote 3 under which the Attorneys General have conducted the investigation.³

9 ³ ALABAMA – Alabama Deceptive Trade Practices Act § 8-19-1 et seq. (2002);
10 ALASKA – Alaska Unfair Trade Practices and Consumer Protection Act AS 45.50.471 –
11 45.50.561; ARIZONA - Consumer Fraud Act, A.R.S. §44-1521 et seq.; ARKANSAS – Arkansas
12 Deceptive Trade Practices Act, Ark. Code Ann. § 4-88-101, et seq.; CALIFORNIA – Bus. & Prof
13 Code §§ 17200 et seq. and 17500 et seq.; COLORADO – Colorado Consumer Protection Act,
14 Colo. Rev. Stat. § 6-1-101 et seq.; CONNECTICUT – Connecticut Unfair Trade Practices Act,
15 Conn. Gen Stat. §§ 42-110a through 42-110q; DELAWARE – Delaware Consumer Fraud Act,
16 Del. CODE ANN. tit. 6, §§ 2511 to 2527; DISTRICT OF COLUMBIA, District of Columbia
17 Consumer Protection Procedures Act, D.C. Code §§ 28-3901 et seq.; FLORIDA – Florida
18 Deceptive and Unfair Trade Practices Act, Part II, Chapter 501, Florida Statutes, 501.201 et. seq.;
19 GEORGIA - Fair Business Practices Act, O.C.G.A. Sections 10-1-390 et seq.; HAWAII –
20 Uniform Deceptive Trade Practice Act, Haw. Rev. Stat. Chpt. 481A and Haw. Rev. Stat. Chpt.
21 480; IDAHO – Idaho Consumer Protection Act, Idaho Code § 48-601 et seq.; ILLINOIS –
22 Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/2 et seq.; INDIANA –
23 Deceptive Consumer Sales Act, Ind. Code §§ 24-5-0.5-0.1 to 24-5-0.5-12; IOWA - Iowa
24 Consumer Fraud Act, Iowa Code Section 714.16; KANSAS - Kansas Consumer Protection Act,
25 K.S.A. 50-623 et seq.; KENTUCKY – Kentucky Consumer Protection Act, KRS Ch. 367.110, et
26 seq.; LOUISIANA – Unfair Trade-Practices and Consumer Protection Law, LSA-R.S. 51:1401,
27 et seq.; MAINE – Unfair Trade Practices Act, 5 M.R.S.A. § 207 et seq.; MARYLAND -
28 Maryland Consumer Protection Act, Md. Code Ann., Com. Law §§ 13-101 et seq.;
MASSACHUSETTS – Mass. Gen. Laws c. 93A, §§ 2 and 4; MICHIGAN – Michigan Consumer
Protection Act, MCL § 445.901 et seq.; MINNESOTA – Minn. Stat. §§325D.44, 325F.69;
MISSISSIPPI - Mississippi Consumer Protection Act, Miss. Code Ann. § 75-24-1, et seq.;
MISSOURI – Missouri Merchandising Practices Act, Mo. Rev. Stat. §§ 407.010 et seq.;
MONTANA – Montana Consumer Protection Act §§ 30-14-101 et seq.; NEBRASKA –
Consumer Protection Act, Neb. Rev. Stat. §§ 59-1601 et seq. and Uniform Deceptive Trade
Practices Act, Neb. Rev. Stat. §§ 87-301 et seq.; NEVADA – Deceptive Trade Practices Act,
Nevada Revised Statutes 598.0903 et seq.; NEW HAMPSHIRE – NH RSA §358-A et seq; NEW
JERSEY – New Jersey Consumer Fraud Act, NJSA 56:8-1 et seq.; NEW MEXICO – NMSA
1978, § 57-12-1 et seq.; NEW YORK – General Business Law Art. 22-A, §§ 349-50, and
Executive Law § 63(12); NORTH CAROLINA – North Carolina Unfair and Deceptive Trade
Practices Act, N.C.G.S. 75-1.1, et seq.; NORTH DAKOTA – Unlawful Sales or Advertising
Practices, N.D. Cent. Code § 51-15-02 et seq.; OHIO – Ohio Consumer Sales Practices Act, R.C.
1345.01, et seq.; OKLAHOMA – Oklahoma Consumer Protection Act 15 O.S. §§ 751 et seq.;
PENNSYLVANIA – Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P.S.
201-1 et seq.; RHODE ISLAND – Deceptive Trade Practices Act, Rhode Island Gen. Laws § 6-
13.1-1, et seq.; SOUTH CAROLINA – South Carolina Unfair Trade Practices Act, S.C. Code
Ann. § 39-5-10 et seq.; SOUTH DAKOTA – South Dakota Deceptive Trade Practices and
Consumer Protection, SDCL ch. 37-24; TENNESSEE – Tennessee Consumer Protection Act,

1 2.16. "BSC Surgical Mesh" means any medical device (as the term "device" is defined in
2 21 U.S.C. § 321(h)) that contains synthetic polypropylene mesh intended to be implanted in the
3 pelvic floor to treat stress urinary incontinence (SUI) and/or pelvic organ prolapse (POP)
4 manufactured and sold by BSC in the United States.

5 2.17. "Valid Scientific Evidence" means evidence from well-controlled investigations,
6 partially controlled studies, studies and objective trials without matched controls, well-documented
7 case histories conducted by qualified experts, and reports of significant human experience with a
8 marketed device, from which it can fairly and responsibly be concluded by qualified experts that
9 there is reasonable assurance of the safety and effectiveness of a device under its conditions of use.

10 2.18. Any reference to a "written document" means a physical paper copy of the
11 document, electronic version of the document, or electronic access to such document.

12 **3. COMPLIANCE PROVISIONS**

13 **A. General Provisions**

14 3.1. Sections 3.3 through 3.26 shall be effective for six years following the Effective
15 Date of this Judgment. Section 3.2 is not time restricted.

16 3.2. BSC shall not violate California Business and Professions Code sections 17200 et
17 seq. or 17500 et seq. in Marketing Materials or when promoting BSC Surgical Mesh.

18 **B. Marketing and Promotional Activities**

19 3.3. BSC shall include all Significant Complications and all Inherent Mesh
20 Complications in its Marketing Materials either by including a list of such complications or a
21 reference to the applicable DFU if the inclusion of a list is not reasonably practicable given the
22 length of the Marketing Material and the media used, such as in reminder ads. Provided however
23 that in all instances where the Marketing Material purports to address the subject of complications,
24 BSC shall include all Significant Complications and all Inherent Mesh Complications.

25 Tenn. Code Ann. 47-18-101 et seq.; TEXAS – Texas Deceptive Trade Practices-Consumer
26 Protection Act, Tex. Bus. And Com. Code 17.41, et seq.; UTAH - Consumer Sales Practices Act,
27 Utah Code Ann. §§ 13-11-1 et seq.; VERMONT – Vermont Consumer Protection Act, 9 V.S.A. §
28 2451, et seq.; VIRGINIA-Virginia Consumer Protection Act, Va Code Ann. §59.1-196 et seq.;
 WASHINGTON – Unfair Business Practices/Consumer Protection Act, RCW §§ 19.86 et seq.;
 and WISCONSIN – Wis. Stat. § 100.18 (Fraudulent Representations).

1 Additionally, in all Marketing Materials that are intended to reach consumers other than or in
2 addition to HCPs and that address the subject of complications, BSC shall include descriptions of
3 the Significant Complications and Inherent Mesh Complications in terms reasonably
4 understandable to a consumer.

5 3.4. BSC shall not, in any Marketing Materials, state or in any way represent that any
6 Inherent Mesh Complications are a risk common to any pelvic floor or other surgery not involving
7 the use of surgical mesh or other graft material.

8 3.5. BSC shall not, in any Marketing Materials, state or in any way represent that
9 Inherent Mesh Complications can be eliminated with surgical experience or technique alone.

10 3.6. BSC shall not, in any Marketing Materials, state or in any way represent that BSC
11 Surgical Mesh does not cause a foreign body reaction, including a chronic foreign body reaction.

12 3.7. BSC shall not, in any Marketing Materials, state or in any way represent that BSC
13 Surgical Mesh remains soft, supple, or pliable, or that it continues to have bi-directional elasticity
14 after the BSC Surgical Mesh is implanted inside the body.

15 3.8. BSC shall not, in any Marketing Materials, state or in any way represent that BSC
16 Surgical Mesh does not potentiate infection or does not increase the likelihood of infection.

17 3.9. BSC shall not, in any Marketing Materials, state or in any way represent that BSC
18 Surgical Mesh is superior to traditional repair unless such representations and claims are supported
19 by Valid Scientific Evidence.

20 3.10. BSC shall not represent that BSC Surgical Mesh is "FDA approved" or that it has
21 undergone the FDA's pre-market approval process, including the requirement for clinical trials,
22 unless such is the case.

23 3.11. In any training provided by or on behalf of BSC to any HCPs regarding proper
24 procedures for insertion and implantation of BSC Surgical Mesh, BSC shall ensure that such
25 training informs the HCP about Significant Complications and Inherent Mesh Complications.

26 3.12. BSC shall not, in any Marketing Materials, misrepresent the complexity of BSC
27 Surgical Mesh implantation procedure or the level of surgical skill and/or experience necessary to
28 perform such a procedure safely.

1 **C. Disclosures to Health Care Providers**

2 3.13. To the extent not prohibited by federal law, BSC shall include all Significant
3 Complications and all Inherent Mesh Complications in the DFUs for BSC Surgical Mesh products.

4 3.14. BSC shall inform purchasers of BSC Surgical Mesh products within the last 24
5 months of FDA Safety Alerts, Product Advisories, Recalls, and Public Health Notices directly
6 relating and applicable to the safety and efficacy of BSC Surgical Mesh as soon as practicable. If
7 BSC obtains, receives, or is aware of any new risk information that necessitates a more immediate
8 disclosure for public health and safety purposes, BSC shall notify said purchasers of this
9 information through other means, such as notices or letters, as appropriate given the nature of the
10 new information.

11 3.15. With respect to BSC Surgical Mesh products, BSC shall comply with all FDA
12 regulations regarding: (1) monitoring device usage and prompt revision of the warnings and
13 precautions section of DFUs based on use experience; (2) reporting adverse events; and (3)
14 collection and dissemination of information pertaining to product safety.

15 **D. Conflicts of Interest**

16 3.16. In all contracts for consulting services regarding Surgical Mesh between BSC and
17 any HCP or other consultant, including contracts for speaking engagements or presentations
18 relating to BSC Surgical Mesh, BSC shall include a Support disclosure provision under which the
19 HCP or other consultant agrees that he or she shall, in terms and in a manner so as to be clearly
20 noticed and understood by the audience, disclose in any public presentation or submission for
21 publication relating to the contracted-for activities, BSC's Support of the contracted-for activities
22 (including all information required by any publication's conflict disclosure requirements). Nothing
23 in this provision is intended to change any requirement in a BSC contract that its prior written
24 consent is required before any HCP or other consultant can present or publish in relation to BSC's
25 contracted-for activities.

26 3.17. In all contracts for BSC-Sponsored studies related to BSC Surgical Mesh, BSC shall
27 require institutions and investigators to properly acknowledge BSC in all publications or
28 presentations resulting from the performance of the Study.

1 3.18. In all contracts for investigator-initiated studies related to BSC Surgical Mesh in
2 which BSC has provided Support, BSC shall require the investigator (if a party to the agreement)
3 and institution to comply with ethical standards concerning publications and authorship in the
4 Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in
5 Medical Journals established by the International Committee of Medical Journal Editors. BSC shall
6 further require that the institution and investigator, if a party to the agreement, properly
7 acknowledge BSC's Support of the Study in publications.

8 **E. Clinical Research**

9 3.19. BSC shall present clinical information regarding BSC Surgical Mesh in a truthful,
10 non-misleading manner and with a balanced presentation of risks in relation to benefits.

11 3.20. BSC shall not, when citing to any clinical study, clinical data, or preclinical data
12 regarding Surgical Mesh, misrepresent the result or scope of the cited information.

13 3.21. BSC shall register all BSC-Sponsored studies regarding its BSC Surgical Mesh with
14 ClinicalTrials.gov as required by 42 CFR Part 11.

15 3.22. BSC shall, when submitting a study or clinical data regarding BSC Surgical Mesh
16 for publication, disclose BSC's role as a Sponsor and any potential conflict of interest with BSC of
17 which BSC is aware for any author consistent with the disclosure requirements for International
18 Committee of Medical Journal Editors (ICMJE).

19 3.23. In relation to BSC Surgical Mesh, BSC shall not, in Marketing Materials, use, rely
20 on, or cite to any clinical study, clinical data or preclinical data where it had control or possession
21 of underlying scientific materials, documents, or raw data on or after November 15, 2012 but does
22 not retain the same for the three-year period following the last date such Marketing Materials are
23 distributed by BSC. This prohibition will not apply if BSC has not retained such underlying
24 scientific materials, documents, or raw data if (1) it was not permitted to retain the underlying
25 scientific materials, documents, or raw data; or (2) the study/data was published in a peer-reviewed
26 journal or has otherwise entered the public domain.

27 3.24. In relation to BSC Surgical Mesh, BSC shall not, in Marketing Materials, use, rely
28 on, or cite to any clinical study, clinical data, preclinical data, research, or article, (1) for which

1 BSC has not complied with the disclosure requirements in paragraph 3.22, unless BSC provides
2 the disclosure detailed in paragraph 3.22 in the Marketing Material that uses, relies on, or cites such
3 clinical study, clinical data, preclinical data, research, or article, (2) Sponsored by BSC for which
4 the institution or investigator has not complied with the disclosure requirements set forth in
5 paragraph 3.17, unless BSC provides the disclosure detailed in paragraph 3.17 in the Marketing
6 Material that uses, relies on, or cites such clinical study, clinical data, preclinical data, research, or
7 article, or (3) Supported by BSC for which any author/consultant/investigator has not complied
8 with the disclosure requirements set forth in paragraphs 3.16 or 3.18, unless BSC discloses the
9 conflict, consistent with the conflict of interest disclosure requirements of the ICMJE, in the
10 Marketing Material that uses, relies on, or cites such clinical study, clinical data, preclinical data,
11 research, or article.

12 **F. Policies and Training**

13 3.25. BSC shall maintain policies requiring that its independent contractors, agents, and
14 employees who sell, market, or promote BSC Surgical Mesh or otherwise communicate with HCPs,
15 nurses, physician's assistants, and other medical professionals, regarding BSC Surgical Mesh, are
16 adequately trained to report patient complaints and/or adverse events to BSC.

17 3.26. BSC shall ensure that its responses to requests for medical information regarding
18 BSC Surgical Mesh and complications associated with BSC Surgical Mesh are accurate and
19 truthful.

20 **G. Monitoring and Compliance**

21 3.27. BSC shall be responsible for monitoring and compliance with the provisions of this
22 Judgment.

23 **4. MONETARY RELIEF**

24 4.1. No Later than 30 days after the Effective Date of this Judgment, BSC shall pay a
25 total amount of One Hundred Eighty-Eight Million, Six Hundred Fifty-Five Thousand, Sixty-Seven
26 Dollars (\$188,655,067).⁴ This amount shall be divided and paid by BSC to each Signatory Attorney
27 General of the Multistate Working Group in an amount to be designated by and in the sole discretion

28 ⁴ The total payment to the State of California shall be \$19,320,785.

1 of the Multistate Executive Committee. The Parties acknowledge that no portion of the payment is
2 a fine or penalty. The payment to California shall be allocated and used by the California Attorney
3 General as provided in California Business and Professions Code section 17206, and to defray the
4 Attorney General's costs in connection with the investigation and litigation leading to the entry of
5 the judgment in this matter.

6 **5. ENFORCEMENT**

7 5.1. For the purposes of resolving disputes with respect to compliance with this
8 Judgment, should any of the Signatory Attorneys General have a reasonable basis to believe that
9 BSC has engaged in a practice that violates a provision of this Judgment subsequent to the Effective
10 Date, then such Attorney General shall notify BSC in writing of the specific objection, identify
11 with particularity the provision of this Judgment that the practice appears to violate, and give BSC
12 thirty (30) days to respond to the notification; provided, however, that a Signatory Attorney General
13 may take any action if the Signatory Attorney General believes that, because of the specific practice,
14 a threat to the health or safety of the public requires immediate action. Upon receipt of written
15 notice, BSC shall provide a good-faith written response to the Signatory Attorney General's
16 notification, containing either a statement explaining why BSC believes it is in compliance with
17 the Judgment, or a detailed explanation of how the alleged violation occurred and a statement
18 explaining how BSC intends to remedy the alleged violation. The Attorney General may agree, in
19 writing, to provide BSC with additional time beyond the thirty (30) days to respond to a notice.
20 Nothing in this section shall be interpreted to limit the State of California's Civil Investigative
21 Demand ("CID") or investigative subpoena authority, to the extent such authority exists under
22 applicable law. BSC reserves all of its rights in responding to a CID or investigative subpoena
23 issued pursuant to such authority.

24 5.2. Upon giving BSC thirty (30) days to respond to the notification described above,
25 the Signatory Attorney General shall also be permitted reasonable access to inspect and copy
26 relevant, non-privileged, non-work product records and documents in the possession, custody, or
27 control of BSC that relate to BSC's compliance with each provision of this Judgment pursuant to
28 that State's CID or investigative subpoena authority. If the Signatory Attorney General makes or

1 requests copies of any documents during the course of that inspection, the Signatory Attorney
2 General will provide a list of those documents to BSC.

3 5.3. The State may assert any claim that BSC has violated this Judgment in a separate
4 civil action to enforce compliance with this Judgment, or may seek any other relief afforded by law
5 for violations of the Judgment, but only after providing BSC an opportunity to respond to the
6 notification described in Paragraph 5.1 above; provided, however, that a Signatory Attorney
7 General may take any action if the Signatory Attorney General believes that, because of the specific
8 practice, a threat to the health or safety of the public requires immediate action.

9 **6. RELEASE**

10 6.1. Released Claims. By its execution of this Judgment, the State of California releases
11 and forever discharges BSC and its past and present officers, directors, shareholders, employees,
12 representatives, agents, affiliates, parents, subsidiaries, predecessors, attorneys, assigns and
13 successors (collectively, the "Releasees") from the following: all civil causes of action, claims,
14 damages, restitution, fines, costs, attorney's fees, remedies or penalties that the California Attorney
15 General has asserted or could have asserted against the Releasees under the State Consumer
16 Protection Statutes resulting from the Covered Conduct up to and including the Effective Date
17 except as set forth in paragraph 6.2 below.

18 6.2. Claims Not Covered. Notwithstanding any term of this Judgment, specifically
19 reserved and excluded from the Released Claims in Paragraph 6.1 as to any entity or person,
20 including Releasees, are any and all of the following, to which BSC expressly reserves each and
21 every available defense:

22 (a) Any criminal liability that any person or entity, including Releasees, has or
23 may have to the State of California;

24 (b) Any civil or administrative liability that any person or entity, including
25 Releasees, has or may have to the State of California not expressly covered by the
26 release in Paragraph 6.1, including, but not limited to, any and all of the following
claims:

27 i. State or federal antitrust violations;

- ii. Claims involving “best price,” “average wholesale price,” “wholesale acquisition cost,” or any reporting practices;
- iii. Medicaid claims, including, but not limited to, federal Medicaid device rebate statute violations, Medicaid fraud or abuse (whether common law, statutory or otherwise), and/or kickback violations related to any state’s Medicaid program;
- iv. State false claims violations; and
- v. Claims to enforce the terms and conditions of this Judgment.

(c) Actions of, or on behalf of, state program payors of the State of California arising from the purchase of BSC Surgical Mesh.

(d) Any claims individual consumers have or may have under any of the above-cited State Consumer Protection Laws against any person or entity, including the Releasees.

6.3. Nothing contained in this Judgment shall relieve BSC of the obligations it maintains under any other Judgment or agreement relating to any of BSC’s products.

7. ADDITIONAL PROVISIONS

7.1. If, subsequent to the Effective Date of this Judgment, the federal government, the FDA, or any state, or any state agency, enacts legislation, regulation, policy or guidance with respect to matters governed by this Judgment that creates a conflict with any provision of the Judgment, and such conflict makes it impossible for BSC to comply with both the newly enacted legislation, regulation, policy, or guidance and the provision of the Judgment that BSC claims is the subject of the conflict, BSC shall provide the Attorney General with notice of the impossible conflict, which shall include an explanation as to how the newly enacted legislation, regulations, policies or guidance creates a conflict and makes it impossible for BSC to comply with the subject provision of the Judgment. The Attorney General shall have thirty (30) days from receipt of the notice to either notify BSC that it agrees to a modification of the Judgment to address the conflict BSC raised, or notify BSC that the Attorney General does not agree that a conflict exists that makes it impossible for BSC to comply with both the legislation, regulation, policy, or guidance and the subject provision of the Judgment, in which case BSC, subject to an Order to the contrary from this

1 Court, must comply with both the newly enacted legislation, regulations, policies or guidance and
2 the provision of the Judgment.

3 7.2. Nothing in this Judgment shall be construed to authorize or require any action by
4 BSC in violation of applicable federal, state, or other laws.

5 7.3. Modification: The Judgment may be modified by a stipulation of the Parties, once
6 it is approved by and becomes a judgment of the Court, or by court proceedings resulting in a
7 modified Judgment of the Court.

8 7.4. BSC shall not cause or encourage third parties, nor knowingly permit third parties
9 acting on its behalf, to engage in practices from which BSC is prohibited by this Judgment.

10 7.5. The Attorney General may, at his or her sole discretion, agree in writing to provide
11 BSC with additional time to perform any act required by this Judgment.

12 7.6. Any failure by any party to this Judgment to insist upon the strict performance by
13 any other party of any of the provisions of this Judgment shall not be deemed a waiver of any of
14 the provisions of this Judgment, and such party, notwithstanding such failure, shall have the right
15 thereafter to insist upon the specific performance of any and all of the provisions of this Judgment.

16 7.7. Entire Agreement: This Judgment and the Stipulation represents the full and
17 complete terms of the settlement entered into by the Parties. In any action undertaken by the Parties,
18 no prior version of this Judgment or the Stipulation and no prior version of any of its terms that
19 were not entered by the Court in this Judgment or the Stipulation, may be introduced for any
20 purpose whatsoever.

21 7.8. Jurisdiction: This Court retains jurisdiction of this Judgment and the Parties for the
22 purpose of enforcing and modifying this Judgment and granting such additional relief as may be
23 necessary and appropriate.

24 7.9. Notice: All Notices under this Judgment shall be provided to the following via email
25 and Overnight Mail:

26 Defendant:

27 BSC:

1 Eileen M. Hunter
2 Vice President
3 Head of Global Litigation
4 Head of Legal Operations
5 4100 Hamline Ave N,
6 St. Paul, MN 55112
7 eileen.hunter@bsci.com

8 CC: Boston Scientific Corporation's attorneys:

9 Joseph Rebein
10 Shook, Hardy & Bacon, L.L.P.
11 2555 Grand Blvd.
12 Kansas City, MO 64018
13 jrebein@shb.com

14 Amy R. Fiterman
15 Faegre Drinker Biddle & Reath LLP
16 2200 Wells Fargo Center
17 90 S. Seventh Street
18 Minneapolis, MN 55402
19 amy.fiterman@faegredrinker.com

20 Signatory Attorney General:

21 Michelle Burkart
22 Deputy Attorney General
23 California Department of Justice
24 300 S. Spring St. Suite 1702
25 Los Angeles, California 90013
26 Michelle.burkart@doj.ca.gov

27 7.10. To the extent that any provision of this Judgment obligates BSC to change any
28 policy(ies) or procedure(s) and to the extent not already accomplished, BSC shall implement the
policy(ies) or procedure(s) as soon as reasonably practicable, but no later than 120 days after the
Effective Date of this Judgment.

BSC will revise its current BSC Surgical Mesh DFUs (the "Current DFUs") to comply
with the terms of this Judgment, including by, among other things, listing all Significant
Complications and Inherent Mesh Complications and ensuring the revised DFU (the "Updated
DFU") conforms with the provisions of Section 3.B, as soon as reasonably practicable, but no later
than 18 months from the Effective Date of this Judgment.

Once there is an Updated DFU available for a product, BSC shall cease packaging that product with the Current DFU.

BSC will make reasonable efforts to deliver Updated DFUs to all HCPs known to implant BSC Surgical Mesh as soon as reasonably practicable after Updated DFUs are available, but no later than 18 months after the Effective Date of this Judgment.

This Judgment does not require BSC to collect or remove pre-existing materials from the public domain. However, BSC shall remove materials available that are inconsistent with this Judgment over which it has control such as materials posted on websites controlled by BSC.

APPROVAL BY COURT

APPROVED FOR FILING and SO ORDERED this 23rd day of March, 2021.

Judge

Tara M. Desautels