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12 **DISTRICT COURT**  
13 **CLARK COUNTY, NEVADA**

14 STATE OF NEVADA, )  
15 )  
Plaintiff, )  
16 )  
vs. )  
17 )  
18 BOSTON SCIENTIFIC CORPORATION )  
19 Defendant. )  
20 )

CASE NO.: A-21-831568-B  
DEPT NO.: 16

**BUSINESS COURT REQUESTED  
ARBITRATION EXEMPTION—  
Action in Equity**

21 **CONSENT JUDGMENT**

22 Plaintiff, State of Nevada, acting by and through its Attorney General, AARON D.  
23 FORD, Consumer Advocate ERNEST D. FIGUEROA, Senior Deputy Attorney General  
24 LAURA M. TUCKER, and Chief Deputy Attorney General JOANN GIBBS, (hereinafter  
25 “State” or “Plaintiff” or “Nevada Attorney General”), has brought this action pursuant to  
26 the provisions of the Nevada Deceptive Trade Practices Act, NRS 598.0903 et seq., having  
27 filed a Complaint against the Defendant.

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1 claims or suits, or any other governmental or regulatory investigations or suits, relating  
2 to the subject matter or terms of this Judgment/Order. This Judgment/Order is made  
3 without trial or adjudication of any issue of fact or law or finding of liability of any kind.  
4 Notwithstanding the foregoing, a State may file an action to enforce the terms of this  
5 Judgment/Order.

6 1.7 It is the intent of the Parties that this Judgment/Order not be admissible in  
7 other cases or binding on BSC in any respect other than in connection with the  
8 enforcement of this Judgment/Order.

9 1.8 No part of this Judgment/Order shall create a private cause of action or  
10 confer any right to any third party for violation of any federal or state statute, except that  
11 a State may file an action to enforce the terms of this Judgment/Order. (Note: Some  
12 states may require state specific modifications to this language.)

13 1.9 This Judgment/Order (or any portion thereof) shall in no way be construed  
14 to prohibit BSC from making representations with respect to any of BSC's products in  
15 Labeling that are required under Federal law, regulations, and policies or guidance  
16 having the force of law.

17 1.10 Nothing in this Judgment/Order shall require BSC to:

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

## 23 II. DEFINITIONS

24 The following definitions shall be used in construing the Judgment/Order:

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  
27 BSC Surgical Mesh products through the Effective Date of the Judgment/Order.

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1           2.2     “Effective Date” means the date on which a copy of the Judgment/Order,  
2 duly executed by BSC and by the Signatory Attorney General, is approved by, and  
3 becomes a Judgment/Order of the Court.

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

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

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

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

26          2.7     “Multistate Executive Committee” means the Attorneys General and their  
27 staffs representing California, Florida, Indiana, Maryland, Ohio, South Carolina, Texas,  
28 and Washington.

1           2.8   “Multistate Working Group” means the Attorneys General and their staffs  
2 representing Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut,  
3 Delaware, District of Columbia, Florida, Georgia, Hawaii<sup>2</sup>, Idaho, Illinois, Indiana, Iowa,  
4 Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota,  
5 Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New  
6 Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode  
7 Island, South Carolina, South Dakota, Tennessee, Texas, Utah<sup>3</sup>, Vermont, Virginia,  
8 Washington, and Wisconsin.

9           2.9   “Parties” means BSC as defined in Section 2.4 and the Signatory Attorney  
10 General.

11           2.10 “Significant Complications” means complications of BSC Surgical Mesh,  
12 including complications discovered subsequent to the Effective Date, which:

- 13           a.    are required to be included in product labeling or advertisements pursuant  
14 to FDA regulations;
- 15           b.    can result in a “serious injury” as defined by 21 CFR § 803.3; or
- 16           c.    include the following complications, which may be ongoing:
- 17                   i.    Pain (pelvic, vaginal, groin/thigh, dyspareunia) (acute or  
18                            chronic);
- 19                   ii.   Foreign body reaction (acute or chronic);
- 20                   iii.   Erosion into organs; exposure/extrusion into vagina;
- 21                   iv.   Dyspareunia;
- 22                   v.    Scarring/scar contracture
- 23                   vi.   Mesh contracture;
- 24                   vii.   Tissue contracture;
- 25                   viii.   Fistula formation (acute or chronic);
- 26                   ix.    Inflammation (acute or chronic);

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27 <sup>2</sup> Hawaii is being represented in this matter by its Office of Consumer Protection, an agency which is not  
28 part of the state Attorney General’s Office, but which is statutorily authorized to undertake consumer  
protection functions, including legal representation of the State 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.

<sup>3</sup> With regard to Utah, the Utah Division of Consumer Protection is charged with administering and  
enforcing the Consumer Sales Practices Act, the statute relevant to this Judgment/Order. References to the  
“States,” “Parties,” or “Attorneys General,” with respect to Utah, refers to the Utah Division of Consumer  
Protection.

- x. Vaginal shortening or stenosis, which may result in dyspareunia and/or sexual dysfunction;
- 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:

- i. 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;
- ii. Removal of mesh or correction of mesh-related complications may involve multiple surgeries;
- iii. 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).

2.12 "Signatory Attorney General" means the Attorney General of the State of Nevada, or his/her authorized designee, who has agreed to this Judgment/Order.

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

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1           2.14 “Support” shall mean financial or product support, or as otherwise defined  
2 as support in a contractual agreement with an HCP or consultant relating to BSC  
3 Surgical Mesh.

4           2.15 “State Consumer Protection Laws” means the consumer protection laws cited  
5 in Footnote 4 under which the Attorneys General have conducted the investigation.<sup>4</sup>

6           2.16 “BSC Surgical Mesh” means any medical device (as the term “device” is  
7 defined in 21 U.S.C. § 321(h)) that contains synthetic polypropylene mesh intended to be  
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9 <sup>4</sup> ALABAMA – Alabama Deceptive Trade Practices Act § 8-19-1 et seq. (2002); ALASKA – Alaska Unfair  
10 Trade Practices and Consumer Protection Act AS 45.50.471 – 45.50.561; ARIZONA - Consumer Fraud Act,  
11 A.R.S. §44-1521 et seq.; ARKANSAS – Arkansas Deceptive Trade Practices Act, Ark. Code Ann. § 4-88-101,  
12 et seq.; CALIFORNIA – Bus. & Prof Code §§ 17200 et seq. and 17500 et seq.; COLORADO – Colorado  
13 Consumer Protection Act, Colo. Rev. Stat. § 6-1-101 et seq.; CONNECTICUT – Connecticut Unfair Trade  
14 Practices Act, Conn. Gen Stat. §§ 42-110a through 42-110q; DELAWARE – Delaware Consumer Fraud Act,  
15 Del. CODE ANN. tit. 6, §§ 2511 to 2527; DISTRICT OF COLUMBIA, District of Columbia Consumer  
16 Protection Procedures Act, D.C. Code §§ 28-3901 et seq.; FLORIDA – Florida Deceptive and Unfair Trade  
17 Practices Act, Part II, Chapter 501, Florida Statutes, 501.201 et. seq.; GEORGIA - Fair Business Practices  
18 Act, O.C.G.A. Sections 10-1-390 et seq.; HAWAII – Uniform Deceptive Trade Practice Act, Haw. Rev. Stat.  
19 Chpt. 481A and Haw. Rev. Stat. Chpt. 480; IDAHO – Idaho Consumer Protection Act, Idaho Code § 48-601  
20 et seq.; ILLINOIS – Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/2 et seq.;  
21 INDIANA – Deceptive Consumer Sales Act, Ind. Code §§ 24-5-0.5-0.1 to 24-5-0.5-12; IOWA - Iowa  
22 Consumer Fraud Act, Iowa Code Section 714.16; KANSAS - Kansas Consumer Protection Act, K.S.A. 50-  
23 623 et seq.; KENTUCKY – Kentucky Consumer Protection Act, KRS Ch. 367.110, et seq.; LOUISIANA –  
24 Unfair Trade-Practices and Consumer Protection Law, LSA-R.S. 51:1401, et seq.; MAINE – Unfair Trade  
25 Practices Act, 5 M.R.S.A. § 207 et seq.; MARYLAND - Maryland Consumer Protection Act, Md. Code Ann.,  
26 Com. Law §§ 13-101 et seq.; MASSACHUSETTS – Mass. Gen. Laws c. 93A, §§ 2 and 4; MICHIGAN –  
27 Michigan Consumer Protection Act, MCL § 445.901 et seq.; MINNESOTA – Minn. Stat. §§325D.44,  
28 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, Tenn. Code  
Ann. 47-18-101 et seq.; TEXAS – Texas Deceptive Trade Practices-Consumer Protection Act, Tex. Bus. And  
Com. Code 17.41, et seq.; UTAH - Consumer Sales Practices Act, Utah Code Ann. §§ 13-11-1 et seq.;  
VERMONT – Vermont Consumer Protection Act, 9 V.S.A. § 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           3.4    BSC shall not, in any Marketing Materials, state or in any way represent  
2 that any Inherent Mesh Complications are a risk common to any pelvic floor or other  
3 surgery not involving the use of surgical mesh or other graft material.

4           3.5    BSC shall not, in any Marketing Materials, state or in any way represent  
5 that Inherent Mesh Complications can be eliminated with surgical experience or  
6 technique alone.

7           3.6    BSC shall not, in any Marketing Materials, state or in any way represent  
8 that BSC Surgical Mesh does not cause a foreign body reaction, including a chronic  
9 foreign body reaction.

10          3.7    BSC shall not, in any Marketing Materials, state or in any way represent  
11 that BSC Surgical Mesh remains soft, supple, or pliable, or that it continues to have bi-  
12 directional elasticity after the BSC Surgical Mesh is implanted inside the body.

13          3.8    BSC shall not, in any Marketing Materials, state or in any way represent  
14 that BSC Surgical Mesh does not potentiate infection or does not increase the likelihood  
15 of infection.

16          3.9    BSC shall not, in any Marketing Materials, state or in any way represent  
17 that BSC Surgical Mesh is superior to traditional repair unless such representations and  
18 claims are supported by Valid Scientific Evidence.

19          3.10   BSC shall not represent that BSC Surgical Mesh is “FDA approved” or that  
20 it has undergone the FDA’s pre-market approval process, including the requirement for  
21 clinical trials, unless such is the case.

22          3.11   In any training provided by or on behalf of BSC to any HCPs regarding  
23 proper procedures for insertion and implantation of BSC Surgical Mesh, BSC shall  
24 ensure that such training informs the HCP about Significant Complications and Inherent  
25 Mesh Complications.

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

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

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

16           **D.     Conflicts of Interest**

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

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1           3.17 In all contracts for BSC-Sponsored studies related to BSC Surgical Mesh,  
2 BSC shall require institutions and investigators to properly acknowledge BSC in all  
3 publications or presentations resulting from the performance of the Study.

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

12           **E.     Clinical Research**

13           3.19 BSC shall present clinical information regarding BSC Surgical Mesh in a  
14 truthful, non-misleading manner and with a balanced presentation of risks in relation to  
15 benefits.

16           3.20 BSC shall not, when citing to any clinical study, clinical data, or preclinical  
17 data regarding Surgical Mesh, misrepresent the result or scope of the cited information.

18           3.21 BSC shall register all BSC-Sponsored studies regarding its BSC Surgical  
19 Mesh with ClinicalTrials.gov as required by 42 CFR Part 11.

20           3.22 BSC shall, when submitting a study or clinical data regarding BSC Surgical  
21 Mesh for publication, disclose BSC's role as a Sponsor and any potential conflict of  
22 interest with BSC of which BSC is aware for any author consistent with the disclosure  
23 requirements for International Committee of Medical Journal Editors (ICMJE).

24           3.23 In relation to BSC Surgical Mesh, BSC shall not, in Marketing Materials,  
25 use, rely on, or cite to any clinical study, clinical data or preclinical data where it had  
26 control or possession of underlying scientific materials, documents, or raw data on or  
27 after November 15, 2012 but does not retain the same for the three-year period following  
28 the last date such Marketing Materials are distributed by BSC. This prohibition will not

1 apply if BSC has not retained such underlying scientific materials, documents, or raw  
2 data if (1) it was not permitted to retain the underlying scientific materials, documents,  
3 or raw data; or (2) the study/data was published in a peer-reviewed journal or has  
4 otherwise entered the public domain.

5       3.24 In relation to BSC Surgical Mesh, BSC shall not, in Marketing Materials,  
6 use, rely on, or cite to any clinical study, clinical data, preclinical data, research, or  
7 article, (1) for which BSC has not complied with the disclosure requirements in  
8 paragraph 3.22, unless BSC provides the disclosure detailed in paragraph 3.22 in the  
9 Marketing Material that uses, relies on, or cites such clinical study, clinical data,  
10 preclinical data, research, or article, (2) Sponsored by BSC for which the institution or  
11 investigator has not complied with the disclosure requirements set forth in paragraph  
12 3.17, unless BSC provides the disclosure detailed in paragraph 3.17 in the Marketing  
13 Material that uses, relies on, or cites such clinical study, clinical data, preclinical data,  
14 research, or article, or (3) Supported by BSC for which any author/consultant/investigator  
15 has not complied with the disclosure requirements set forth in paragraphs 3.16 or 3.18,  
16 unless BSC discloses the conflict, consistent with the conflict of interest disclosure  
17 requirements of the ICMJE, in the Marketing Material that uses, relies on, or cites such  
18 clinical study, clinical data, preclinical data, research, or article.

19       **F. Policies and Training**

20       3.25 BSC shall maintain policies requiring that its independent contractors,  
21 agents, and employees who sell, market, or promote BSC Surgical Mesh or otherwise  
22 communicate with HCPs, nurses, physician's assistants, and other medical professionals,  
23 regarding BSC Surgical Mesh, are adequately trained to report patient complaints and/or  
24 adverse events to BSC.

25       3.26 BSC shall ensure that its responses to requests for medical information  
26 regarding BSC Surgical Mesh and complications associated with BSC Surgical Mesh are  
27 accurate and truthful.

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1 following: all civil causes of action, claims, damages, restitution, fines, costs, attorney's  
2 fees, remedies or penalties that the Nevada Attorney General has asserted or could have  
3 asserted against the Released Parties under the State Consumer Protection Statutes  
4 resulting from the Covered Conduct up to and including the Effective Date except as set  
5 forth in paragraph 6.2 below.

6       6.2    Claims Not Covered. Notwithstanding any term of this Judgment/Order,  
7 specifically reserved and excluded from the Released Claims in Paragraph 6.1 as to any  
8 entity or person, including Releasees, are any and all of the following, to which BSC  
9 expressly reserves each and every available defense:

- 10           (a)    Any criminal liability that any person or entity, including Releasees, has or  
11                    may have to the State of Nevada;
- 12           (b)    Any civil or administrative liability that any person or entity, including  
13                    Releasees, has or may have to the State of Nevada not expressly covered by  
14                    the release in Paragraph 6.1, including, but not limited to, any and all of the  
15                    following claims:
- 16                    i.     State or federal antitrust violations;
- 17                    ii    Claims involving "best price," "average wholesale price," "wholesale  
18                        acquisition cost," or any reporting practices;
- 19                    iii.   Medicaid claims, including, but not limited to, federal Medicaid device  
20                        rebate statute violations, Medicaid fraud or abuse (whether common  
21                        law, statutory or otherwise), and/or kickback violations related to any  
22                        state's Medicaid program;
- 23                    iv.    State false claims violations; and
- 24                    v.     Claims to enforce the terms and conditions of this Judgment/Order.
- 25           (c)    Actions of, or on behalf of, state program payors of the State of Nevada  
26                    arising from the purchase of BSC Surgical Mesh.
- 27           (d)    Any claims individual consumers have or may have under any of the above-  
28                    cited State Consumer Protection Laws against any person or entity,  
                  including the Releasees.

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

1 **VII. ADDITIONAL PROVISIONS**

2 7.1 If, subsequent to the Effective Date of this Judgment/Order, the federal  
3 government, the FDA, or any state, or any state agency, enacts legislation, regulation,  
4 policy or guidance with respect to matters governed by this Judgment/Order that creates  
5 a conflict with any provision of the Judgment/Order, and such conflict makes it  
6 impossible for BSC to comply with both the newly enacted legislation, regulation, policy,  
7 or guidance and the provision of the Judgment/Order that BSC claims is the subject of  
8 the conflict, BSC shall provide the Attorney General with notice of the impossible conflict,  
9 which shall include an explanation as to how the newly enacted legislation, regulations,  
10 policies or guidance creates a conflict and makes it impossible for BSC to comply with the  
11 subject provision of the Judgment/Order. The Attorney General shall have thirty (30)  
12 days from receipt of the notice to either notify BSC that it agrees to a modification of the  
13 Judgment/Order to address the conflict BSC raised, or notify BSC that the Attorney  
14 General does not agree that a conflict exists that makes it impossible for BSC to comply  
15 with both the legislation, regulation, policy, or guidance and the subject provision of the  
16 Judgment/Order, in which case BSC, subject to an Order to the contrary from this Court,  
17 must comply with both the newly enacted legislation, regulations, policies or guidance  
18 and the provision of the Judgment/Order.

19 7.2 Nothing in this Judgment/Order shall be construed to authorize or require  
20 any action by BSC in violation of applicable federal, state, or other laws.

21 7.3 Modification: The Judgment/Order may be modified by a stipulation of the  
22 Parties, once it is approved by and becomes a judgment of the Court, or by court  
23 proceedings resulting in a modified Judgment of the Court.

24 7.4 BSC shall not cause or encourage third parties, nor knowingly permit third  
25 parties acting on its behalf, to engage in practices from which BSC is prohibited by this  
26 Judgment/Order.

27 7.5 The Attorney General may, at his or her sole discretion, agree in writing to  
28 provide BSC with additional time to perform any act required by this Judgment/Order.



1           7.6     The acceptance of this Judgment/Order by the State of Nevada shall not be  
2 deemed approval by the State of Nevada of any of BSC's advertising or business practices.  
3 Further, neither BSC nor anyone acting on its behalf shall state or imply, or cause to be  
4 stated or implied, that the State of Nevada or any other governmental unit of the State of  
5 Nevada has approved, sanctioned or authorized any practice, act, advertisement, or  
6 conduct of BSC.

7           7.7     Any failure by any party to this Judgment/Order to insist upon the strict  
8 performance by any other party of any of the provisions of this Judgment/Order shall not  
9 be deemed a waiver of any of the provisions of this Judgment/Order, and such party,  
10 notwithstanding such failure, shall have the right thereafter to insist upon the specific  
11 performance of any and all of the provisions of this Judgment/Order.

12           7.8     Entire Agreement: This Judgment/Order represents the full and complete  
13 terms of the settlement entered into by the Parties. In any action undertaken by the  
14 Parties, no prior version of this Judgment/Order and no prior version of any of its terms  
15 that were not entered by the Court in this Judgment/Order, may be introduced for any  
16 purpose whatsoever.

17           7.9     Jurisdiction: This Court retains jurisdiction of this Judgment/Order and the  
18 Parties for the purpose of enforcing and modifying this Judgment/Order and granting  
19 such additional relief as may be necessary and appropriate.

20           7.10    Notice: All Notices under this Judgment/Order shall be provided to the  
21 following via email and Overnight Mail:

22           BSC:

23  
24           Eileen M. Hunter  
25           Vice President  
26           Head of Global Litigation  
27           Head of Legal Operations  
28           4100 Hamline Ave N,  
              St. Paul, MN 55112  
              eileen.hunter@bsci.com

1 CC: Boston Scientific Corporation's attorneys:

2 Joseph Rebein  
3 Shook, Hardy & Bacon, L.L.P.  
4 2555 Grand Blvd.  
5 Kansas City, MO 64018  
6 jrebein@shb.com

7 Amy R. Fiterman  
8 Faegre Drinker Biddle & Reath LLP  
9 2200 Wells Fargo Center  
10 90 S. Seventh Street  
11 Minneapolis, MN 55402  
12 amy.fiterman@faegredrinker.com

13 Signatory Attorney General:

14 Laura M. Tucker  
15 Senior Deputy Attorney General  
16 Office of the Nevada Attorney General's Bureau of Consumer Protection  
17 8945 W. Russell Road, Suite 204  
18 Las Vegas, NV 89148  
19 702-486-6525  
20 LMTucker@ag.nv.gov

21 7.11 To the extent that any provision of this Judgment/Order obligates BSC to  
22 change any policy(ies) or procedure(s) and to the extent not already accomplished, BSC  
23 shall implement the policy(ies) or procedure(s) as soon as reasonably practicable, but no  
24 later than 120 days after the Effective Date of this Judgment/Order.

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

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

///


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

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

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9 Approved:

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For Defendant Boston Scientific Corporation



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Eileen Hunter  
Vice President  
Head of Global Litigation  
Head of Legal Operations

3-17-21

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1 Local Counsel for Boston Scientific Corporation

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3 \_\_\_\_\_

4 Jenn Odell Hatcher  
5 Nevada Bar No. 14248  
6 Shook, Hardy & Bacon LLP  
7 2555 Grand Blvd.  
8 Kansas City, MO 64018  
9 jhatcher@shb.com

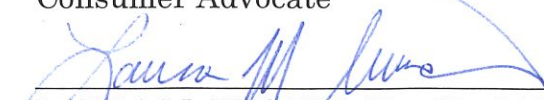
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For Plaintiff:

AARON D. FORD  
Attorney General  
ERNEST D. FIGUEROA  
Consumer Advocate

  
\_\_\_\_\_  
LAURA M. TUCKER (Bar No. 013268)  
Senior Deputy Attorney General

Date: 03/17/2021