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10 **IN THE SUPERIOR COURT OF THE STATE OF ARIZONA**

11 **IN AND FOR THE COUNTY OF MARICOPA**

12 STATE OF ARIZONA, *ex rel.* MARK
13 BRNOVICH, Attorney General,

14 Plaintiff,

15 v.

16 BOSTON SCIENTIFIC CORPORATION,
17

18 Defendant.

Case No. _____

CONSENT JUDGMENT

(Assigned to the Hon. _____)

19
20 Plaintiff, the State of Arizona, ex rel. Mark Brnovich, the Attorney General (“Arizona” or
21 “Plaintiff”) has filed a Complaint for a permanent injunction and other relief in this matter
22 pursuant to the Arizona Consumer Fraud Act, A.R.S. §§ 44-1521 to -1534 (the “CFA”) alleging
23 that Defendant Boston Scientific Corporation (“BSC” or “Defendant”) committed violations of
24 the Act. Defendant has waived service of the complaint, has been advised of the right to a trial
25 in this matter, and has waived the same. Plaintiff, by its counsel, and Defendant, by its counsel,
26 have agreed to the entry of this Consent Judgment by the Court without trial or adjudication of
27 any issue of fact or law and without finding or admission of wrongdoing or liability of any kind.

28 . . .

1 **IT IS HEREBY ORDERED THAT:**

2 **I. FINDINGS**

3 1.1 The State is authorized to bring this action under the CFA.

4 1.2 Defendant is Boston Scientific Corporation, a Delaware corporation, incorporated
5 June 22, 1979, with its principal headquarters located at 300 Boston Scientific Way,
6 Marlborough, MA 01752.

7 1.3 All events, acts and practices described in, and relevant to, this Consent Judgment
8 took place in Arizona.

9 1.4 This Court has jurisdiction over the subject matter of this lawsuit and over all
10 Parties.

11 1.5 Venue is proper in Maricopa County pursuant to A.R.S. § 12-401.

12 1.6 The terms of this Consent Judgment shall be governed by the laws of the State of
13 Arizona.

14 1.7 The State of Arizona contends that entry of this Consent Judgment is in the public
15 interest. The Consent Judgment reflects a negotiated agreement among the Parties.

16 1.8 BSC is willing to enter into this Consent Judgment regarding the Covered Conduct
17 to resolve the Attorney General's concerns under the State Consumer Protection Laws as to the
18 matters addressed in this Consent Judgment and thereby avoid significant expense,
19 inconvenience, and uncertainty.

20 1.9 The Parties have agreed to resolve the issues raised by the Covered Conduct by
21 entering into this Consent Judgment.¹

22 1.10 BSC is entering into this Consent Judgment solely for the purpose of settlement,
23 and nothing contained herein may be taken as or construed to be an admission or concession of
24 any violation of law, rule, or regulation, or of any other matter of fact or law, or of any liability
25 or wrongdoing, all of which BSC expressly denies. BSC does not admit any violation of the
26 State Consumer Protection Laws set forth in Footnote 4, and does not admit any wrongdoing

27 _____
28 ¹ This agreement is entered into pursuant to and subject to the State Consumer Protection laws
cited in Footnote 4.

1 that was or could have been alleged by any Attorney General before the date of the Consent
2 Judgment under those laws. No part of this Consent Judgment, including its statements and
3 commitments, shall constitute evidence of any liability, fault, or wrongdoing by BSC. This
4 document and its contents are not intended for use by any third party for any purpose, including
5 submission to any court for any purpose. This Consent Judgment shall not be construed or used
6 as a waiver or limitation of any defense otherwise available to BSC in any other action, or of
7 BSC's right to defend itself from, or make any arguments in, any private individual or class
8 action claims or suits, or any other governmental or regulatory investigations or suits, relating to
9 the subject matter or terms of this Consent Judgment. This Consent Judgment is made without
10 trial or adjudication of any issue of fact or law or finding of liability of any kind.
11 Notwithstanding the foregoing, a State may file an action to enforce the terms of this Consent
12 Judgment.

13 1.11 It is the intent of the Parties that this Consent Judgment not be admissible in other
14 cases or binding on BSC in any respect other than in connection with the enforcement of this
15 Consent Judgment.

16 1.12 No part of this Consent Judgment shall create a private cause of action or confer
17 any right to any third party for violation of any federal or state statute, except that a State may
18 file an action to enforce the terms of this Consent Judgment.

19 1.13 This Consent Judgment (or any portion thereof) shall in no way be construed to
20 prohibit BSC from making representations with respect to any of BSC's products in Labeling
21 that are required under Federal law, regulations, and policies or guidance having the force of
22 law.

23 1.14 Nothing in this Consent Judgment shall require BSC to:

- 24 (a) take any action that is prohibited by the Federal Food, Drug and Cosmetic Act,
25 21 U.S.C. § 301 *et seq.* ("FDCA") or any regulation promulgated thereunder
26 or by the FDA; or
27 (b) fail to take any action that is required by the FDA, or by the FDCA or any
28 regulation promulgated thereunder.

1 **II. DEFINITIONS**

2 The following definitions shall be used in construing the Consent Judgment:

3 2.1 “Covered Conduct” means BSC’s marketing and promotional practices and
4 dissemination of information to Health Care Providers (HCPs) or consumers regarding BSC
5 Surgical Mesh products through the Effective Date of the Consent Judgment.

6 2.2 “Effective Date” means the date on which a copy of the Consent Judgment, duly
7 executed by BSC and by the Signatory Attorney General, is approved by, and becomes a
8 Consent Judgment of the Court.

9 2.3 “Health Care Provider” or “HCP” means any physician who in the course of his or
10 her practice may prescribe or implant BSC Surgical Mesh.

11 2.4 “BSC” or “Defendant” means Boston Scientific Corporation, and all of its
12 officers, directors, employees, representatives, agents, affiliates, parents, subsidiaries, operating
13 companies, assigns, and successors.

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

20 2.6 “Marketing Materials” means any written or electronic material, or written or
21 verbal statements either publicly disseminated or made by or on behalf of BSC for the purpose
22 of public dissemination to induce a sale or purchase in the United States in the course of
23 marketing, promoting, or informing Health Care Providers, nurses, physician’s assistants, other
24 medical professionals, and consumers about BSC Surgical Mesh, including: Directions for Use
25 (DFUs), pamphlets, brochures, Frequently Asked Questions (FAQs), sales representative
26 training materials containing material or statements intended to be publicly disseminated, HCP
27 training materials, communications with HCPs, presentations (including poster presentations
28 . . .

1 and abstract presentations), seminars, videos, advertisements in any form of media, and websites
2 hosted or controlled by BSC.

3 2.7 “Multistate Executive Committee” means the Attorneys General and their staffs
4 representing California, Florida, Indiana, Maryland, Ohio, South Carolina, Texas, and
5 Washington.

6 2.8 “Multistate Working Group” means the Attorneys General and their staffs
7 representing Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware,
8 District of Columbia, Florida, Georgia, Hawaii², Idaho, Illinois, Indiana, Iowa, Kansas,
9 Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi,
10 Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York,
11 North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina,
12 South Dakota, Tennessee, Texas, Utah³, Vermont, Virginia, Washington, and Wisconsin.

13 2.9 “Parties” means BSC as defined in Section 2.4 and the Signatory Attorney
14 General.

15 2.10 “Significant Complications” means complications of BSC Surgical Mesh,
16 including complications discovered subsequent to the Effective Date, which:

- 17 a. are required to be included in product labeling or advertisements pursuant
18 to FDA regulations;
- 19 b. can result in a “serious injury” as defined by 21 CFR § 803.3; or
- 20 c. include the following complications, which may be ongoing:
- 21 i. Pain (pelvic, vaginal, groin/thigh, dyspareunia) (acute or chronic);

22
23 ² Hawaii is being represented in this matter by its Office of Consumer Protection, an agency
24 which is not part of the state Attorney General’s Office, but which is statutorily authorized to
25 undertake consumer protection functions, including legal representation of the State of Hawaii.
26 For simplicity, the entire group will be referred to as the “Attorneys General,” and such
27 designation, as it includes Hawaii, refers to the Executive Director of the State of Hawaii Office
28 of Consumer Protection.

³ 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.

- 1 ii. Foreign body reaction (acute or chronic);
- 2 iii. Erosion into organs; exposure/extrusion into vagina;
- 3 iv. Dyspareunia;
- 4 v. Scarring/scar contracture
- 5 vi. Mesh contracture;
- 6 vii. Tissue contracture;
- 7 viii. Fistula formation (acute or chronic);
- 8 ix. Inflammation (acute or chronic);
- 9 x. Vaginal shortening or stenosis, which may result in dyspareunia
- 10 and/or sexual dysfunction;
- 11 xi. Pain with intercourse that may not resolve;
- 12 xii. Exposed mesh may cause pain or discomfort to the patient's partner
- 13 during intercourse;
- 14 xiii. Infection;
- 15 xiv. Sexual dysfunction; including the inability to have intercourse;
- 16 xv. De novo detrusor instability;
- 17 xvi. Voiding dysfunction (incontinence, temporary or permanent lower
- 18 urinary tract obstruction, difficulty urinating, pain with urination, overactive bladder);
- 19 xvii. Bruising, bleeding (vaginal, hematoma formation);
- 20 xviii. Abscess;
- 21 xix. Dehiscence of vaginal incision;
- 22 xx. Perforation or laceration of vessels, nerves, bladder, urethra, or
- 23 bowel may occur during placement; and
- 24 xxi. Failure to resolve a patient's stress urinary incontinence

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

27 . . .

1 i. The occurrence of one or more of these complications may require
2 treatment or surgical intervention. In some instances, the complication may persist as a
3 permanent condition after the surgical intervention or other treatment;

4 ii. Removal of mesh or correction of mesh-related complications may involve
5 multiple surgeries;

6 iii. Complete removal of mesh may not be possible and additional surgeries
7 may not always fully correct the complications.

8 2.11 “Inherent Mesh Complications” shall include significant complications associated
9 with the use of the mesh material that may not be eliminated with surgical technique (as opposed
10 to non-mesh surgery).

11 2.12 “Signatory Attorney General” means the Attorney General of the State of Arizona,
12 or his authorized designee, who has agreed to this Consent Judgment.

13 2.13 “Sponsor” is the organization or person who initiates a study and who has
14 authority and control over a study relating to BSC Surgical Mesh.

15 2.14 “Support” shall mean financial or product support, or as otherwise defined as
16 support in a contractual agreement with an HCP or consultant relating to BSC Surgical Mesh.

17 2.15 “State Consumer Protection Laws” means the consumer protection laws cited in
18 Footnote 4 under which the Attorneys General have conducted the investigation.⁴

19
20 ⁴ ALABAMA – Alabama Deceptive Trade Practices Act § 8-19-1 et seq. (2002); ALASKA –
21 Alaska Unfair Trade Practices and Consumer Protection Act AS 45.50.471 – 45.50.561;
22 ARIZONA – Consumer Fraud Act, A.R.S. §44-1521 et seq.; ARKANSAS – Arkansas
23 Deceptive Trade Practices Act, Ark. Code Ann. § 4-88-101, et seq.; CALIFORNIA – Bus. &
24 Prof Code §§ 17200 et seq. and 17500 et seq.; COLORADO – Colorado Consumer Protection
25 Act, Colo. Rev. Stat. § 6-1-101 et seq.; CONNECTICUT – Connecticut Unfair Trade Practices
26 Act, Conn. Gen Stat. §§ 42-110a through 42-110q; DELAWARE – Delaware Consumer Fraud
27 Act, Del. CODE ANN. tit. 6, §§ 2511 to 2527; DISTRICT OF COLUMBIA, District of
28 Columbia Consumer Protection Procedures Act, D.C. Code §§ 28-3901 et seq.; FLORIDA –
Florida Deceptive and Unfair Trade Practices Act, Part II, Chapter 501, Florida Statutes,
501.201 et. seq.; GEORGIA - Fair Business Practices Act, O.C.G.A. Sections 10-1-390 et seq.;
HAWAII – Uniform Deceptive Trade Practice Act, Haw. Rev. Stat. Chpt. 481A and Haw.
Rev. Stat. Chpt. 480; IDAHO – Idaho Consumer Protection Act, Idaho Code § 48-601 et seq.;
ILLINOIS – Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/2 et seq.;

1 2.16 “BSC Surgical Mesh” means any medical device (as the term “device” is defined
2 in 21 U.S.C. § 321(h)) that contains synthetic polypropylene mesh intended to be implanted in
3 the 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
6

7 INDIANA – Deceptive Consumer Sales Act, Ind. Code §§ 24-5-0.5-0.1 to 24-5-0.5-12; IOWA
8 - Iowa Consumer Fraud Act, Iowa Code Section 714.16; KANSAS - Kansas Consumer
9 Protection Act, K.S.A. 50-623 et seq.; KENTUCKY – Kentucky Consumer Protection Act,
10 KRS Ch. 367.110, et seq.; LOUISIANA – Unfair Trade-Practices and Consumer Protection
11 Law, LSA-R.S. 51:1401, et seq.; MAINE – Unfair Trade Practices Act, 5 M.R.S.A. § 207 et
12 seq.; MARYLAND - Maryland Consumer Protection Act, Md. Code Ann., Com. Law §§ 13-
13 101 et seq.; MASSACHUSETTS – Mass. Gen. Laws c. 93A, §§ 2 and 4; MICHIGAN –
14 Michigan Consumer Protection Act, MCL § 445.901 et seq.; MINNESOTA – Minn. Stat.
15 §§325D.44, 325F.69; MISSISSIPPI - Mississippi Consumer Protection Act, Miss. Code Ann. §
16 75-24-1, et seq.; MISSOURI – Missouri Merchandising Practices Act, Mo. Rev. Stat. §§
17 407.010 et seq.; MONTANA – Montana Consumer Protection Act §§ 30-14-101 et seq.;
18 NEBRASKA – Consumer Protection Act, Neb. Rev. Stat. §§ 59-1601 et seq. and Uniform
19 Deceptive Trade Practices Act, Neb. Rev. Stat. §§ 87-301 et seq.; NEVADA – Deceptive
20 Trade Practices Act, Nevada Revised Statutes 598.0903 et seq.; NEW HAMPSHIRE – NH RSA
21 §358-A et seq.; NEW JERSEY – New Jersey Consumer Fraud Act, NJSA 56:8-1 et seq.; NEW
22 MEXICO – NMSA 1978, § 57-12-1 et seq.; NEW YORK – General Business Law Art. 22-A,
23 §§ 349-50, and Executive Law § 63(12); NORTH CAROLINA – North Carolina Unfair and
24 Deceptive Trade Practices Act, N.C.G.S. 75-1.1, et seq.; NORTH DAKOTA – Unlawful Sales
25 or Advertising Practices, N.D. Cent. Code § 51-15-02 et seq.; OHIO – Ohio Consumer Sales
26 Practices Act, R.C. 1345.01, et seq.; OKLAHOMA – Oklahoma Consumer Protection Act 15
27 O.S. §§ 751 et seq.; ; PENNSYLVANIA – Pennsylvania Unfair Trade Practices and Consumer
28 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).

Wash

1 3.5 BSC shall not, in any Marketing Materials, state or in any way represent that
2 Inherent Mesh Complications can be eliminated with surgical experience or technique alone.

3 3.6 BSC shall not, in any Marketing Materials, state or in any way represent that BSC
4 Surgical Mesh does not cause a foreign body reaction, including a chronic foreign body reaction.

5 3.7 BSC shall not, in any Marketing Materials, state or in any way represent that BSC
6 Surgical Mesh remains soft, supple, or pliable, or that it continues to have bi-directional
7 elasticity after the BSC Surgical Mesh is implanted inside the body.

8 3.8 BSC shall not, in any Marketing Materials, state or in any way represent that BSC
9 Surgical Mesh does not potentiate infection or does not increase the likelihood of infection.

10 3.9 BSC shall not, in any Marketing Materials, state or in any way represent that BSC
11 Surgical Mesh is superior to traditional repair unless such representations and claims are
12 supported by Valid Scientific Evidence.

13 3.10 BSC shall not represent that BSC Surgical Mesh is “FDA approved” or that it has
14 undergone the FDA’s pre-market approval process, including the requirement for clinical trials,
15 unless such is the case.

16 3.11 In any training provided by or on behalf of BSC to any HCPs regarding proper
17 procedures for insertion and implantation of BSC Surgical Mesh, BSC shall ensure that such
18 training informs the HCP about Significant Complications and Inherent Mesh Complications.

19 3.12 BSC shall not, in any Marketing Materials, misrepresent the complexity of BSC
20 Surgical Mesh implantation procedure or the level of surgical skill and/or experience necessary
21 to perform such a procedure safely.

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

23 3.13 To the extent not prohibited by federal law, BSC shall include all Significant
24 Complications and all Inherent Mesh Complications in the DFUs for BSC Surgical Mesh
25 products.

26 3.14 BSC shall inform purchasers of BSC Surgical Mesh products within the last 24
27 months of FDA Safety Alerts, Product Advisories, Recalls, and Public Health Notices directly
28 relating and applicable to the safety and efficacy of BSC Surgical Mesh as soon as practicable.

1 If BSC obtains, receives, or is aware of any new risk information that necessitates a more
2 immediate disclosure for public health and safety purposes, BSC shall notify said purchasers of
3 this information through other means, such as notices or letters, as appropriate given the nature
4 of the new information.

5 3.15 With respect to BSC Surgical Mesh products, BSC shall comply with all FDA
6 regulations regarding: (1) monitoring device usage and prompt revision of the warnings and
7 precautions section of DFUs based on use experience; (2) reporting adverse events; and (3)
8 collection and dissemination of information pertaining to product safety.

9 **D. Conflicts of Interest**

10 3.16 In all contracts for consulting services regarding Surgical Mesh between BSC and
11 any HCP or other consultant, including contracts for speaking engagements or presentations
12 relating to BSC Surgical Mesh, BSC shall include a Support disclosure provision under which
13 the HCP or other consultant agrees that he or she shall, in terms and in a manner so as to be
14 clearly noticed and understood by the audience, disclose in any public presentation or
15 submission for publication relating to the contracted-for activities, BSC's Support of the
16 contracted-for activities (including all information required by any publication's conflict
17 disclosure requirements). Nothing in this provision is intended to change any requirement in a
18 BSC contract that its prior written consent is required before any HCP or other consultant can
19 present or publish in relation to BSC's contracted-for activities.

20 3.17 In all contracts for BSC-Sponsored studies related to BSC Surgical Mesh, BSC
21 shall require institutions and investigators to properly acknowledge BSC in all publications or
22 presentations resulting from the performance of the Study.

23 3.18 In all contracts for investigator-initiated studies related to BSC Surgical Mesh in
24 which BSC has provided Support, BSC shall require the investigator (if a party to the
25 agreement) and institution to comply with ethical standards concerning publications and
26 authorship in the Recommendations for the Conduct, Reporting, Editing, and Publication of
27 Scholarly Work in Medical Journals established by the International Committee of Medical
28 . . .

1 Journal Editors. BSC shall further require that the institution and investigator, if a party to the
2 agreement, properly acknowledge BSC's Support of the Study in publications.

3 **E. Clinical Research**

4 3.19 BSC shall present clinical information regarding BSC Surgical Mesh in a truthful,
5 non-misleading manner and with a balanced presentation of risks in relation to benefits.

6 3.20 BSC shall not, when citing to any clinical study, clinical data, or preclinical data
7 regarding Surgical Mesh, misrepresent the result or scope of the cited information.

8 3.21 BSC shall register all BSC-Sponsored studies regarding its BSC Surgical Mesh
9 with ClinicalTrials.gov as required by 42 CFR Part 11.

10 3.22 BSC shall, when submitting a study or clinical data regarding BSC Surgical Mesh
11 for publication, disclose BSC's role as a Sponsor and any potential conflict of interest with BSC
12 of which BSC is aware for any author consistent with the disclosure requirements for
13 International Committee of Medical Journal Editors (ICMJE).

14 3.23 In relation to BSC Surgical Mesh, BSC shall not, in Marketing Materials, use, rely
15 on, or cite to any clinical study, clinical data or preclinical data where it had control or
16 possession of underlying scientific materials, documents, or raw data on or after November 15,
17 2012 but does not retain the same for the three-year period following the last date such
18 Marketing Materials are distributed by BSC. This prohibition will not apply if BSC has not
19 retained such underlying scientific materials, documents, or raw data if (1) it was not permitted
20 to retain the underlying scientific materials, documents, or raw data; or (2) the study/data was
21 published in a peer-reviewed journal or has otherwise entered the public domain.

22 3.24 In relation to BSC Surgical Mesh, BSC shall not, in Marketing Materials, use, rely
23 on, or cite to any clinical study, clinical data, preclinical data, research, or article, (1) for which
24 BSC has not complied with the disclosure requirements in paragraph 3.22, unless BSC provides
25 the disclosure detailed in paragraph 3.22 in the Marketing Material that uses, relies on, or cites
26 such clinical study, clinical data, preclinical data, research, or article, (2) Sponsored by BSC for
27 which the institution or investigator has not complied with the disclosure requirements set forth
28 in paragraph 3.17, unless BSC provides the disclosure detailed in paragraph 3.17 in the

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

7 **F. Policies and Training**

8 3.25 BSC shall maintain policies requiring that its independent contractors, agents, and
9 employees who sell, market, or promote BSC Surgical Mesh or otherwise communicate with
10 HCPs, nurses, physician's assistants, and other medical professionals, regarding BSC Surgical
11 Mesh, are adequately trained to report patient complaints and/or adverse events to BSC.

12 3.26 BSC shall ensure that its responses to requests for medical information regarding
13 BSC Surgical Mesh and complications associated with BSC Surgical Mesh are accurate and
14 truthful.

15 **G. Monitoring and Compliance**

16 3.27 BSC shall be responsible for monitoring and compliance with the provisions of
17 this Consent Judgment.

18 **IV. MONETARY RELIEF**

19 4.1 No Later than 30 days after the Effective Date of this Consent Judgment, BSC
20 shall pay a total amount of One Hundred Eighty-Eight Million, Six Hundred Fifty-Five
21 Thousand, Sixty-Seven Dollars (\$188,655,067). This amount shall be divided and paid by BSC
22 to each Signatory Attorney General of the Multistate Working Group in an amount to be
23 designated by and in the sole discretion of the Multistate Executive Committee. The Parties
24 acknowledge that no portion of the payment is a fine or penalty. The payment shall be deposited
25 into the Consumer Protection-Consumer Fraud Revolving Fund pursuant to A.R.S. § 44-
26 1531.01, and used in any of the following ways in accordance with the purposes set forth
27 therein: (1) to pay for attorney's fees and other costs of investigation and litigation; (2) to place
28 in, or apply to, consumer protection enforcement, including future consumer protection

1 enforcement, consumer education, litigation, or local consumer aid or revolving funds; (3) to
2 defray the costs of the inquiry leading to this final Consent Judgment; and/or (4) for any lawful
3 purpose, at the sole discretion of each Signatory Attorney General.

4 **V. ENFORCEMENT**

5 5.1 For the purposes of resolving disputes with respect to compliance with this
6 Consent Judgment, should any of the Signatory Attorneys General have a reasonable basis to
7 believe that BSC has engaged in a practice that violates a provision of this Consent Judgment
8 subsequent to the Effective Date, then such Attorney General shall notify BSC in writing of the
9 specific objection, identify with particularity the provision of this Consent Judgment that the
10 practice appears to violate, and give BSC thirty (30) days to respond to the notification;
11 provided, however, that a Signatory Attorney General may take any action if the Signatory
12 Attorney General believes that, because of the specific practice, a threat to the health or safety of
13 the public requires immediate action. Upon receipt of written notice, BSC shall provide a good-
14 faith written response to the Signatory Attorney General's notification, containing either a
15 statement explaining why BSC believes it is in compliance with the Consent Judgment, or a
16 detailed explanation of how the alleged violation occurred and a statement explaining how BSC
17 intends to remedy the alleged violation. The Attorney General may agree, in writing, to provide
18 BSC with additional time beyond the thirty (30) days to respond to a notice. Nothing in this
19 section shall be interpreted to limit the State of Arizona's Civil Investigative Demand ("CID")
20 or investigative subpoena authority, to the extent such authority exists under applicable law.
21 BSC reserves all of its rights in responding to a CID or investigative subpoena issued pursuant
22 to such authority.

23 5.2 Upon giving BSC thirty (30) days to respond to the notification described above,
24 the Signatory Attorney General shall also be permitted reasonable access to inspect and copy
25 relevant, non-privileged, non-work product records and documents in the possession, custody, or
26 control of BSC that relate to BSC's compliance with each provision of this Consent Judgment
27 pursuant to that State's CID or investigative subpoena authority. If the Signatory Attorney
28 ...

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

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

10 VI. RELEASE

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

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

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

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

28 i. State or federal antitrust violations;

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

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

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

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

13 7.6 The acceptance of this Consent Judgment by Arizona shall not be deemed
14 approval by Arizona of any of BSC's advertising or business practices. Further, neither BSC
15 nor anyone acting on its behalf shall state or imply, or cause to be stated or implied, that Arizona
16 or any other governmental unit of Arizona has approved, sanctioned or authorized any practice,
17 act, advertisement, or conduct of BSC.

18 7.7 Any failure by any party to this Consent Judgment to insist upon the strict
19 performance by any other party of any of the provisions of this Consent Judgment shall not be
20 deemed a waiver of any of the provisions of this Consent Judgment, and such party,
21 notwithstanding such failure, shall have the right thereafter to insist upon the specific
22 performance of any and all of the provisions of this Consent Judgment.

23 7.8 Entire Agreement: This Consent Judgment represents the full and complete terms
24 of the settlement entered into by the Parties. In any action undertaken by the Parties, no prior
25 version of this Consent Judgment and no prior version of any of its terms that were not entered
26 by the Court in this Consent Judgment, may be introduced for any purpose whatsoever.

27 ...

28 ...

1 7.9 Jurisdiction: This Court retains jurisdiction of this Consent Judgment and the
2 Parties for the purpose of enforcing and modifying this Consent Judgment and granting such
3 additional relief as may be necessary and appropriate.

4 7.10 Notice: All Notices under this Consent Judgment shall be provided to the
5 following via email and Overnight Mail:

6 BSC:

7 Boston Scientific Corporation

8 Eileen M. Hunter

9 Vice President

10 Head of Global Litigation

11 Head of Legal Operations

12 4100 Hamline Ave N,

13 St. Paul, MN 55112

14 eileen.hunter@bsci.com

15 CC: Boston Scientific Corporation's attorneys:

16 Joseph Rebein

17 Shook, Hardy & Bacon, L.L.P.

18 2555 Grand Blvd.

19 Kansas City, MO 64018

20 jrebein@shb.com

21 Amy R. Fiterman

22 Faegre Drinker Biddle & Reath LLP

23 2200 Wells Fargo Center

24 90 S. Seventh Street

25 Minneapolis, MN 55402

26 amy.fiterman@faegredrinker.com

27 Signatory Attorney General:

28 Consumer Protection and Advocacy Section

 The Office of the Arizona Attorney General

 2005 N. Central Ave.

 Phoenix, AZ 85004

 7.11 To the extent that any provision of this Consent Judgment obligates BSC to
change any policy(ies) or procedure(s) and to the extent not already accomplished, BSC shall

1 implement the policy(ies) or procedure(s) as soon as reasonably practicable, but no later than
2 120 days after the Effective Date of this Consent Judgment.

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

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

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

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

17 7.12 This Consent Judgment may be executed by the parties in counterparts and be
18 delivered by facsimile or electronic transmission, or a copy thereof, such constituting an original
19 counterpart hereof, all of which together will constitute one and the same document.

20 7.13 This Consent Judgment resolves all outstanding claims expressly identified in the
21 Complaint as to Defendant. As no further matters remain pending, this is a final judgment
22 entered pursuant to Ariz. R. Civ. P. 54(c).

23 **APPROVAL BY COURT**

24 APPROVED FOR FILING and SO ORDERED this ____ day of _____, 2021.
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26
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JUDGE OF THE SUPERIOR COURT

CONSENT TO JUDGMENT

1
2 1. Defendant acknowledges that it has waived service of the Summons and
3 Complaint, has read the Findings of Fact, Conclusions of Law and Order, and is aware of its
4 right to a trial in this matter and has waived the same.

5 2. Defendant admits the jurisdiction of this Court and consents to the entry of the
6 foregoing Findings of Fact and Conclusions of Law and Order.

7 3. Defendant states that no promise of any kind or nature whatsoever was made to
8 induce it to enter into this Consent Judgment and declares that it has entered into this Consent
9 Judgment voluntarily.

10 4. This Consent Judgment is entered as a result of a compromise and a settlement
11 agreement between the parties. Only the State may seek enforcement of this Consent Judgment.
12 Nothing herein is intended to create a private right of action by other parties; however, this
13 Consent Judgment does not limit the rights of any private party to pursue any remedies allowed
14 by law.

15 5. This Consent to Judgment may be executed in counterparts and be delivered by
16 facsimile or electronic transmission, or a copy thereof, such constituting an original counterpart
17 hereof, all of which together will constitute one and the same document.

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