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Docket Number

COMMONWEALTH OF MASSACHUSETTS

MIDDLESEX, SS.	**SUPERIOR COURT DEPARTMENT** **CIVIL ACTION NO.: _____**
DANIEL PATRICK MARCHIO and ROSE MARIE MARCHIO, **Plaintiffs,** **v.** **BOSTON SCIENTIFIC CORPORATION,** **Defendant.**	10/14/2026 RECEIVED NH

COMPLAINT

Plaintiffs, by and through counsel, file this Complaint against Boston Scientific Corporation as follows:

PARTIES, JURISDICTION AND VENUE

1.

Plaintiff Daniel Patrick Marchio is a seventy-four-year-old male who is married to Rose Marie Marchio. Mr. Marchio underwent placement of either SpaceOAR Vue on March 17, 2023 at UPMC Hanover in Hanover, Pennsylvania.

2.

Boston Scientific Corporation ("Boston Scientific") is the manufacturer of SpaceOAR and SpaceOAR Vue.

3.

Boston Scientific is headquartered at 300 Boston Scientific Way, Marlborough, Massachusetts 01752.

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Boston Scientific is subject to both general jurisdiction and specific jurisdiction in this Court.

5.

Venue is proper in this Court.

FACTS

6.

On October 1, 2014, Augmenix Inc. filed a De Novo request to the United States Food and Drug Administration ("FDA") for approval of the SpaceOAR System (“SpaceOAR”) as a Class II medical device.

7.

A De Novo request provides a pathway for FDA approval of a lower risk medical device (Class I or II) in order to bypass the FDA’s more stringent Class III Premarket Approval (PMA) review.

8.

In its De Novo application, Augmenix claimed to the FDA that the “[r]isk of a harmful event is low as there were no device-related serious or non-serious adverse events.”

9.

The FDA approved Augmenix’s De Novo request on April 1, 2015 as a Class II medical device governed by 21 C.F.R.§ 892.5725 (Absorbable perirectal spacer) with special controls.

10.

The FDA requires SpaceOAR to include “risk management activities as part of the manufacturer’s § 820.30 design controls must document an appropriate end user initial training program which will be offered as part of efforts to mitigate the risk of failure to correctly operate

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the device, including, but not limited to, documentation of an appropriate end user initial training program on the proper spacer deployment technique." 21 C.F.R.§ 892.5725(b)(2).

11.

The FDA requires SpaceOAR to include the following device labeling: "a detailed summary of reported or observed complications related to the use of the device" and "appropriate warnings." 21 C.F.R.§ 892.5725(b)(3)(i) and (ii).

12.

Augmenix, Inc. was acquired by Boston Scientific in 2018.

13.

On July 19, 2019, the FDA approved Augmenix, Inc.'s Section 510(k) premarket notification of intent to market SpaceOAR Vue as a Class II medical device governed by 21 C.F.R.§ 892.5725 (Absorbable perirectal spacer). SpaceOAR Vue was subject to the same controls as SpaceOAR.

14.

SpaceOAR Vue is a second-generation, radiopaque product. The predicate device, SpaceOAR, is not radiopaque.

15.

SpaceOAR and SpaceOAR Vue are designed to protect the rectum (the end portion of the large intestine adjoining the anal canal) from the adverse effects of radiation aimed to kill cancer cells in the prostate.

16.

Because the prostate is adjacent to the rectum, spillover radiation targeted for the prostate may reach the rectum.

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17.

Without the use of a rectal spacer such as SpaceOAR, patients may occasionally experience rectal irritation or rectal bleeding from the spillover effect of radiation.

18.

SpaceOAR was designed to reduce the occasional rectal irritation or rectal bleeding from prostate radiation.

19.

The benefit of SpaceOAR is minimal, but worth it, as long as the risks of SpaceOAR are insignificant.

20.

The primary problem with SpaceOAR and SpaceOAR Vue is the significant elevated risk of gel infiltrating the rectal wall and, combined with radiation, eroding the rectal wall and causing a hole (a fistula).

21.

A hole may develop between the prostate and rectum (rectoprostatic fistula) or a hole may develop between the rectum and urethra (rectourethral fistula) caused by SpaceOAR infiltrating the rectal wall and additive radiation further degrading the tissue.

22.

A rectoprostatic fistula or rectourethral fistula causes pain, inflammation, infections, and urine exiting the body through the anus.

23.

Treatment for a rectoprostatic fistula or rectourethral fistula typically involves diverting stool away from the rectum by attaching the large intestine to the abdomen (colostomy bag) and

by diverting urine away from the urethra (suprapubic catheter).

24.

SpaceOAR is designed to be injected via ultrasound guidance into the perirectal space, the space between the prostate and the rectum.

25.

SpaceOAR is not supposed to be enter the rectal wall (the cellular layers lining the circumference of the rectum).

26.

The perirectal space is hard to visualize, even with ultrasound guidance. Once air is introduced into the perirectal space through the SpaceOAR plunger (used to deploy the gel), visualization of the location of the gel is further compromised by the introduction of air obscuring the ultrasound waves.

27.

Due to the challenge of inserting gel into the perirectal space, gel tends to migrate or infiltrate (enter) into the rectal wall.

28.

Since at least as early as January 1, 2023, Boston Scientific has been aware that SpaceOAR and SpaceOAR Vue would infiltrate the rectal wall for at least ten percent (10%) of patients.

29.

Because of this significant elevated risk with SpaceOAR, many major academic health centers and hospital systems do not use SpaceOAR or SpaceOAR Vue.

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30.

It is a well-known maxim in medicine that an ounce of prevention is worth a pound of cure. A corollary that applies to SpaceOAR is that the prevention should not cause more harm the disease itself.

31.

Prior to the use of rectal spacers, it was (and still is without the use of SpaceOAR) exceedingly rare (less than a half of one percent) for a prostate cancer patient to develop a fistula from the spillover effect of radiation.

32.

Since at least as early as January 1, 2023, Boston Scientific has been aware that the use of SpaceOAR has INCREASED not decreased the incidence rate of fistulas for prostate cancer patients.

33.

SpaceOAR Vue was designed for the gel to be more readily identified on computed tomography (CT) imaging.

34.

While SpaceOAR Vue is more readily identified on CT than SpaceOAR, magnetic resonance imaging (MRI) is the gold standard for identification of rectal wall gel infiltration due to MRI's shaper, more detailed imaging of soft tissue.

35.

If MRI reveals rectal wall infiltration of the gel, the standard of care for SpaceOAR use should require that radiation is postponed until the gel is absorbed in the body.

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If a rectal wall is infiltrated with gel, adding radiation to the infiltrated rectal wall increases the likelihood of fistulas exponentially.

37.

Since at least as early as January 1, 2023, Boston Scientific has been aware that the best practice for use of SpaceOAR requires that an MRI be performed after placement of the gel to evaluate for rectal wall infiltration of the gel prior to the initiation of radiation therapy.

38.

Since at least as early as January 1, 2023, Boston Scientific's knowledge of the hazards of radiating the rectal wall with a known rectal wall infiltration of SpaceOAR is far superior to the knowledge of practicing physicians who have comparatively limited experience with the complications associated with the use of SpaceOAR.

39.

Since at least as early as January 1, 2023, despite its superior knowledge, Boston Scientific has failed to recommend that physicians obtain an MRI after SpaceOAR placement, prior to administering radiation.

40.

Since at least as early as January 1, 2023, despite its superior knowledge, Boston Scientific has failed to recommend that physicians refrain from radiating the prostate/rectal wall with a known rectal wall infiltration of SpaceOAR.

41.

On September 2, 2022, Daniel Marchio underwent prostate biopsy for a suspicion of prostate cancer.

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The September 2, 2022 biopsy revealed adenocarcinoma involving 4/13 cores: the right medial mid (Gleason score 4+4=8 involving 10% of tissue cores), the right lateral mid (Gleason score 4+4=8 involving 30% of tissue cores), the right lateral apex (Gleason score 4+4=8 involving 80% of tissue cores), the right apex peripheral zone (Gleason score 5+3=8 involving 70% of tissue cores),

43.

On October 6, 2022, Mr. Marchio underwent PSMA PET CT with no evidence of metastatic disease.

44.

Testing revealed Mr. Marchio's prostate cancer as Stage T1c N0 M0 high risk with a Gleason score of 8 (3+5) and a PSA of 9.48.

45.

Glenn B. Mieszkalski, M.D., a radiation oncologist, recommended triple therapy for prostate cancer treatment: hormonal deprivation, low dose radiation brachytherapy and external beam radiation.

46.

Michael H. Kane, M.D., a urologist, agreed with Dr. Mieszkalski's recommendation for triple therapy for Mr. Marchio.

47.

Dr. Kane performed brachytherapy low dose radiation seed placement on January 9, 2023 at University of Pittsburgh Medical Center ("UPMC') Hanover.

48.

On March 17, 2023, Dr. Kane placed the SpaceOAR Vue at UPMC Hanover.

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49.

On March 27, 2023, Mr. Marchio underwent MRI at UPMC Memorial for evaluation of the placement of SpaceOAR Vue.

50.

The March 27, 2023 MRI revealed a moderate amount of SpaceOAR Vue had infiltrated the rectal wall.

51.

On April 3, 2023, Dr. Mieszkalski began the first external beam radiation therapy at UPMC Hillman Cancer Center.

52.

Dr. Mieszkalski administered twenty-five (25) treatments of 180cGy for a total of 4500cGy to Mr. Marchio at UPMC Hillman Cancer Center, ending on May 5, 2023.

53.

On August 17, 2023, an MRI of the pelvis at UPMC Hanover revealed a fistula in the rectum at the location of the SpaceOAR Vue.

54.

On September 20, 2023, Mr. Marchio had a follow-up appointment with Dr. Mieszkalski at UPMC Hillman Cancer Center. Dr. Mieszkalski told Mr. Marchio that his fistula was due to "undiagnosed underlying inflammatory bowel disease."

55.

On October 26, 2023, Mr. Marchio had a follow-up visit with Dr. Kane at UPMC Pinnacle Urology. Dr. Kane told Mr. Marchio that he needed treatment for inflammatory bowel disease.

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56.

Contrary to the information conveyed to Mr. Marchio by Dr. Mieszkalski and Dr. Kane, Mr. Marchio's fistula was not caused by inflammatory bowel disease. Mr. Marchio had a fistula caused by external beam radiation incorrectly administered after an MRI confirmed SpaceOAR Vue hydrogel infiltrated in the rectal wall.

57.

Until April of 2026, Mr. and Mrs. Marchio were unaware that SpaceOAR Vue was the cause of the fistula.

58.

On March 21, 2024, Mr. Marchio presented to Matthew Kaag, M.D., a urologist, at Milton S. Hershey Medical Center for evaluation of his rectourethral fistula. Dr. Kaag planned for surgical procedures with colorectal surgery to provide care and treatment for Mr. Marchio's fistula.

59.

On April 25, 2024, Mr. Marchio was admitted to Hershey Medical Center for the surgical procedures.

60.

On April 25, 2024, Dr. Kaag performed a diagnostic colonoscopy, cystoscopy, and the placement of a suprapubic catheter.

61.

On April 25, 2024, Michael Deutsch, a colorectal surgeon, performed a loop sigmoid colostomy to divert stool away from the fistula to promote healing.

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The diagnostic procedure performed on April 25, 2024 confirmed (diagnostically) for the first time a large rectourethral fistula.

63.

Mr. Marchio was discharged from Hershey Medical Center on April 29, 2024.

64.

On June 26, 2024, Mr. Marchio returned to Hershey Medical Center for a diagnostic cystoscopy to evaluate the fistula and for a suprapubic catheter exchange.

65.

Damage to the rectal wall caused by radiation administered to a rectum with hydrogel infiltrated in the rectal wall generally will take months for the injury (damage to the rectal wall) to evolve.

66.

Due to the surgical intervention on April 25, 2024 and due to the progressive evolution of a rectal wall injury due to radiation and gel, June 26, 2024 marked the first time that Mr. Marchio's rectal wall injury began to heal.

67.

On August 23, 2024, Mr. Marchio returned to Hershey Medical Center for a diagnostic cystoscopy to evaluate the fistula and for a suprapubic catheter exchange.

68.

On August 23, 2024, Mr. Marchio returned to Hershey Medical Center for a diagnostic cystoscopy to evaluate the fistula and for a suprapubic catheter exchange. After the procedure, Dr. Kaag discussed with Mr. and Mrs. Marchio that the only possible treatment for his fistula was pelvic reconstructive surgery.

69.

Mr. Marchio has incurred medical expenses in excess of $300,000.00 due to rectal wall gel infiltration, rectal wall ulceration due to the gel infiltration, rectourethral fistula, a colostomy with a colostomy bag for fecal diversion, and a suprapubic catheter for urinary diversion.

COUNT I

STRICT PRODUCT LIABILITY FOR DEFECTIVE DESIGN AGAINST BOSTON SCIENTIFIC CORPORATION

70.

Plaintiffs allege and incorporate by reference herein each and every allegation set forth in Paragraphs 1 through 69 of this Complaint.

71.

Defendant Boston Scientific Corporation is strictly liable to Plaintiffs because of a design defect which made the SpaceOAR Vue unreasonably dangerous to the consumer.

72.

The SpaceOAR Vue is defective because the risks inherent in the product design outweigh the utility or benefit derived from the product.

73.

The design defects in the SpaceOAR Vue include, but are not limited to, the following:

(a) a design that is prone to insertion of the gel into the rectal wall;

(b) a design that make it difficult to contain the gel within the proper anatomical location—the perirectal space; and

(c) a design that does not allow for easy removal of the gel if inserted inadvertently into the rectal wall.

74.

The design defects in the SpaceOAR Vue directly and proximately caused Daniel Patrick Marchio to suffer rectal wall gel infiltration, rectal wall ulceration due to the gel infiltration, rectourethral fistula, a colostomy with a colostomy bag for fecal diversion, and a suprapubic catheter for urinary diversion.

COUNT II

STRICT PRODUCT LIABILITY FOR DEFECTIVE WARNING AGAINST BOSTON SCIENTIFIC CORPORATION

75.

Plaintiffs allege and incorporate by reference herein each and every allegation set forth in Paragraphs 1 through 74 of this Complaint.

76.

Defendant Boston Scientific Corporation is liable to Plaintiffs because SpaceOAR Vue was defective due to inadequate product warnings which caused the product to be unreasonably dangerous to Daniel Patrick Marchio.

77.

The inadequate product warnings proximately caused Daniel Patrick Marchio's gel infiltration, ulceration of the rectal wall, rectourethral fistula, a colostomy with a colostomy bag for fecal diversion, and a suprapubic catheter for urinary diversion.

78.

Based on Pennsylvania product liability law, medical device manufacturers are required to adequately warn physicians of foreseeable risks associated with the use of a device.

79.

Physicians are required to weigh a product's risks and benefits when advising patients on the use of a product.

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80.

Physicians are not armed with the same data as Boston Scientific.

81.

The product warnings issued by Boston Scientific to physicians are defective due to:

(a) a failure to provide the rate of rectal wall infiltrations for patients receiving SpaceOAR Vue;

(b) a failure to provide the rate of rectal wall infiltrations for patients who do not receive a rectal spacer;

(c) a failure to provide the rate of rectal wall ulcerations for patients receiving SpaceOAR Vue;

(d) a failure to provide the rate of rectal wall ulcerations for patients who do not receive a rectal spacer;

(e) a failure to provide the rate of fistulas for patients receiving SpaceOAR Vue;

(f) a failure to provide the rate of fistulas for patients who do not receive a rectal spacer;

(g) a failure to provide the rate of bowel diversions for patients receiving SpaceOAR Vue;

(h) a failure to provide the rate of bowel diversions for patients who do not receive a rectal spacer;

(i) a failure to provide the rate of urinary diversions for patients receiving SpaceOAR Vue;

(j) a failure to provide the rate of urinary diversions for patients who do not receive a rectal spacer;

(k) a failure to warn physicians to obtain MRI to confirm placement of SpaceOAR Vue;

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and

(l) a failure to warn physicians to refrain from radiating patients who have infiltration of gel in the rectal wall.

82.

Because Boston Scientific fails to provide this data, physicians are not aware of the catastrophic complications caused by gel infiltration in the rectal wall resulting in ulceration, fistula, colostomy, and urinary diversion.

83.

Because physicians are not aware of the prevalence of catastrophic risks associated with the use of SpaceOAR Vue, physicians are not able to make their own informed decisions or allow their patients to make informed decisions by weighing the actual risks and benefits of SpaceOAR Vue.

84.

As a direct and proximate result of Boston Scientific failing to adequately warn physicians, Daniel Patrick Marchio suffered gel infiltration, ulceration of the rectal wall, a rectourethral fistula, a colostomy with a colostomy bag for fecal diversion, and a suprapubic catheter for urinary diversion.

COUNT III

CLAIM FOR NEGLIGENT DESIGN
AGAINST BOSTON SCIENTIFIC CORPORATION

85.

Plaintiffs allege and incorporate by reference herein each and every allegation set forth in Paragraphs 1 through 84 of this Complaint.

86.

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Defendant Boston Scientific Corporation is liable to Plaintiffs due to a negligent design of SpaceOAR Vue.

87.

Boston Scientific breached a duty to exercise reasonable care by:

(a) designing a product that is prone to insertion of the gel into the rectal wall;

(b) designing a product that is unreasonably difficult to contain the gel within the proper anatomical location—the perirectal space; and

(c) designing a product that does not allow for easy removal of the gel if inserted inadvertently into the rectal wall.

88.

The negligent design of SpaceOAR Vue caused an unreasonable risk of injury to Daniel Patrick Marchio.

89.

The negligent design of SpaceOAR Vue directly and proximately caused Daniel Patrick Marchio to suffer rectal wall gel infiltration, rectal wall ulceration due to the gel infiltration, rectourethral fistula, a colostomy with a colostomy bag for fecal diversion, and a suprapubic catheter for urinary diversion.

COUNT IV

CLAIM FOR NEGLIGENT WARNING AGAINST BOSTON SCIENTIFIC CORPORATION

90.

Plaintiffs allege and incorporate by reference herein each and every allegation set forth in Paragraphs 1 through 89 of this Complaint.

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Defendant Boston Scientific Corporation is liable to Plaintiffs due to an inadequate warning which caused SpaceOAR Vue to be unreasonably dangerous to Daniel Patrick Marchio.

92.

The inadequate product warnings proximately caused Daniel Patrick Marchio's gel infiltration, ulceration of the rectal wall, rectourethral fistula, a colostomy with a colostomy bag for fecal diversion, and a suprapubic catheter for urinary diversion.

93.

Medical device manufacturers are required to adequately warn physicians of foreseeable risks associated with the use of a device.

94.

The FDA requires SpaceOAR Vue to include "risk management activities as part of the manufacturer's § 820.30 design controls must document an appropriate end user initial training program which will be offered as part of efforts to mitigate the risk of failure to correctly operate the device, including, but not limited to, documentation of an appropriate end user initial training program on the proper spacer deployment technique." 21 C.F.R.§ 892.5725(b)(2).

95.

The FDA requires SpaceOAR Vue to include the following device labeling: "a detailed summary of reported or observed complications related to the use of the device" and "appropriate warnings." 21 C.F.R.§ 892.5725(b)(3)(i) and (ii).

96.

Physicians are required to weigh a product's risks and benefits when advising patients on the use of a product.

97.

Physicians are not armed with the same data as Boston Scientific.

98.

The product warnings issued by Boston Scientific and the end user training program provided by Boston Scientific to physicians are inadequate due to:

(a) a failure to provide the rate of rectal wall infiltrations for patients receiving SpaceOAR Vue;

(b) a failure to provide the rate of rectal wall infiltrations for patients who do not receive a rectal spacer;

(c) a failure to provide the rate of rectal wall ulcerations for patients receiving SpaceOAR Vue;

(d) a failure to provide the rate of rectal wall ulcerations for patients who do not receive a rectal spacer;

(e) a failure to provide the rate of fistulas for patients receiving SpaceOAR Vue;

(f) a failure to provide the rate of fistulas for patients who do not receive a rectal spacer;

(g) a failure to provide the rate of bowel diversions for patients receiving SpaceOAR Vue;

(h) a failure to provide the rate of bowel diversions for patients who do not receive a rectal spacer;

(i) a failure to provide the rate of urinary diversions for patients receiving SpaceOAR Vue;

(j) a failure to provide the rate of urinary diversions for patients who do not receive a rectal spacer;

(k) a failure to warn physicians to obtain MRI to confirm placement of SpaceOAR Vue;

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and

(l) a failure to warn physicians to refrain from radiating patients who have infiltration of gel in the rectal wall.

99.

Because Boston Scientific fails to provide this data, physicians are not aware of the catastrophic complications caused by gel infiltration in the rectal wall resulting in ulceration, fistula, colostomy, and urinary diversion.

100.

Because physicians are not aware of the prevalence of catastrophic risks associated with the use of SpaceOAR Vue, physicians are not able to make their own informed decisions or allow their patients to make informed decisions by weighing the actual risks and benefits of SpaceOAR Vue.

101.

As a direct and proximate result of Boston Scientific failing to adequately warn physicians, Daniel Patrick Marchio suffered gel infiltration, ulceration of the rectal wall, a rectourethral fistula, a colostomy with a colostomy bag for fecal diversion, and a suprapubic catheter for urinary diversion.

COUNT V

CLAIM FOR LOSS OF CONSORTIUM AGAINST BOSTON SCIENTIFIC CORPORATION

102.

Plaintiff Rose Marie Marchio alleges and incorporates by reference herein each and every allegation set forth in Paragraphs 1 through 101 of this Complaint.

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Plaintiff Rose Marie Marchio seeks compensation for the loss of companionship, affection, intimacy and household services caused by her husband's injuries.

circumstances and for their costs.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendants, individually, jointly and severally, as follows:

a. for general and compensatory damages in an amount to be proven at the time of trial;

b. for special damages in an amount to be proven at the time of trial;

c. for statutory damages as set forth above, in an amount to be proven at the time of trial;

d. for exemplary and punitive damages in an amount to be proven at the time of trial, and sufficient to punish Defendants or to deter Defendants and others from repeating the injurious conduct alleged herein;

e. for pre-judgment and post-judgment interest on the above general and special damages;

f. for costs of this suit and attorneys' fees; and

g. all other relief that this Court deems necessary, proper and just.

PLAINTIFF REQUESTS A TRIAL BY JURY ON ALL COUNTS.

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This 14th day of October, 2026.

Plaintiffs,
By Their Attorney,

/s/ Jonathan D. Orent, Esq.
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