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COMMONWEALTH OF MASSACHUSETTS

MIDDLESEX, SS.	**SUPERIOR COURT DEPARTMENT** **CIVIL ACTION NO.: _____**
TODD WILLIAM WADDLE and CHERYL NELSON WADDLE, **Plaintiffs,** **v.** **BOSTON SCIENTIFIC CORPORATION,** **Defendant.**	NH RECEIVED 10/14/2026

COMPLAINT

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

PARTIES, JURISDICTION AND VENUE

1.

Plaintiff Todd William Waddle is a seventy-two-year-old male who is married to Cheryl Nelson Waddle. Mr. Waddle underwent placement of either SpaceOAR or SpaceOAR Vue on January 6, 2026 at Baptist Health Care in Pensacola, Florida.

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 July 22, 2025, Todd Waddle underwent a prostate biopsy for suspicion of prostate cancer.

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Mr. Waddle was diagnosed with Stage cT1c favorable intermediate risk with Gleason score 7 (3+4) adenocarcinoma of the prostate and a PSA of 6.04.

43.

Warren Amos, M.D., a radiation oncologist with SunState Medical Specialists, suggested that Mr. Waddle undergo radiation treatment with hormone therapy.

44.

Mr. Waddle started hormone therapy via Lupron injection with Kapil Puri, M.D., urologist, on December 4, 2025.

45.

A repeat PSA on December 5, 2025 showed a value of 8.3.

46.

In anticipation of radiation therapy, urologist Ryan K. Miyamoto, M.D. placed Mr. Waddle's gold fiducial markers and SpaceOAR on January 6, 2026 at Baptist Health Care.

47.

Following the marker and SpaceOAR placement, Dr. Amos proceeded with simulation and treatment planning on January 12, 2026.

48.

On January 22, 2026, Dr. Amos began the first intensity-modulated radiation therapy treatment at SunState Medical Specialists.

49.

Dr. Amos administered 25 radiation treatments of 2.72Gy for a total of 68Gy to Mr. Waddle at SunState Medical Specialists, ending on February 27, 2026.

50.

Following radiation, Mr. Waddle experienced pain and rectal discomfort.

51.

Mr. Waddle underwent a colonoscopy on June 10, 2026 with Andrew Ringle, M.D. at Emerald Coast Surgery Center which revealed a rectal wall ulceration at the site of the SpaceOAR. Dr. Ringle referred Mr. Waddle back to Dr. Amos for evaluation.

52.

On June 10, 2026, Dr. Amos prescribed Mr. Waddle pentoxifylline and referred Mr. Waddle for hyperbaric oxygen treatment. to promote healing of the rectal wall ulceration. Dr. Amos ordered a cystoscopy and an MRI of the pelvis.

53.

An MRI of the pelvis was performed on July 8, 2026 at Twin Cities Hospital. The MRI revealed a rectal wall ulceration at the site of the SpaceOAR.

54.

On July 13, 2026, Mr. Waddle had a follow-up appointment with Dr. Amos to review the results of the MRI. Dr. Amos noted that Mr. Waddle remained in significant pain.

55.

On July 13, 2026, Dr. Amos informed Mr. Waddle that he (Dr. Amos) had reached out to Boston Scientific for treatment options of the rectal wall ulceration.

56.

At Boston Scientific's recommendation, Dr. Amos consulted with Paul Nguyen, M.D., a radiation oncologist from Brigham and Women's Hospital in Boston, Massachusetts.

57.

Dr. Nguyen is a medical advisor for Boston Scientific on SpaceOAR. Boston Scientific has referred several physicians across the country to Dr. Nguyen for advice regarding the management of rectal wall infiltration and fistula from SpaceOAR.

58.

On July 15, 2026, Dr. Amos entered a note into the medical record that Dr. Nguyen attributed the fistula to SpaceOAR.

59.

Dr. Amos referred Mr. Waddle to Emory University Hospital in Atlanta, Georgia.

60.

Mr. Waddle presented to Emory University Hospital on July 16, 2026 for an appointment with Patrick S. Sullivan, M.D., colorectal surgeon. Mr. Waddle underwent a cystoscopy and flexible sigmoidoscopy that revealed a rectal ulceration. Mr. Waddle was referred for further hyperbaric oxygen treatment.

61.

Mr. Waddle has undergone hyperbaric oxygen treatment at Ascension Sacred Heart with his last day of HBO treatment scheduled for October 15, 2026. Mr. Waddle will have another MRI following HBO to re-evaluate his healing.

62.

Mr. Waddle continues to experience significant pain, even while taking oxycodone. If the pain continues, a diverting colostomy may be necessary.

63.

Prior to the SpaceOAR placement, Mr. Waddle was very active and exercised regularly. He would play pickleball three (3) times a week for an hour and a half each time, went on

multiple walks per week, hiked and rode bikes with his seven (7) grandchildren, and was an avid golfer. Since the SpaceOAR placement, Mr. Waddle is very limited in his physical activities due to the pain.

64.

Mr. Waddle has incurred medical expenses in excess of $50,000.00 due to rectal wall gel infiltration, rectal wall ulceration due to the gel infiltration, and a rectoprostatic fistula.

COUNT I

STRICT PRODUCT LIABILITY FOR DEFECTIVE DESIGN AGAINST BOSTON SCIENTIFIC CORPORATION

65.

Plaintiffs allege and incorporate by reference herein each and every allegation set forth in Paragraphs 1 through 64 of this Complaint.

66.

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

67.

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

68.

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

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into the rectal wall.

69.

The design defects in the SpaceOAR Vue directly and proximately caused Todd William Waddle to suffer rectal wall gel infiltration, rectal wall ulceration due to the gel infiltration, and a rectoprostatic fistula.

COUNT II

STRICT PRODUCT LIABILITY FOR DEFECTIVE WARNING 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 liable to Plaintiffs because SpaceOAR Vue was defective due to inadequate product warnings which caused the product to be unreasonably dangerous to Todd William Waddle.

72.

The inadequate product warnings proximately caused Todd William Waddle's gel infiltration, ulceration of the rectal wall, and rectoprostatic fistula.

73.

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

74.

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

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the use of a product.

75.

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

76.

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; and

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

77.

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.

78.

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.

79.

As a direct and proximate result of Boston Scientific failing to adequately warn physicians, Todd William Waddle suffered gel infiltration, ulceration of the rectal wall, and a rectoprostatic fistula.

COUNT III

CLAIM FOR NEGLIGENT DESIGN AGAINST BOSTON SCIENTIFIC CORPORATION

80.

Plaintiffs allege and incorporate by reference herein each and every allegation set forth in Paragraphs 1 through 79 of this Complaint.

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81.

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

82.

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.

83.

The negligent design of SpaceOAR Vue caused an unreasonable risk of injury to Todd William Waddle.

84.

The negligent design of SpaceOAR Vue directly and proximately caused Todd William Waddle to suffer rectal wall gel infiltration, rectal wall ulceration due to the gel infiltration, and a rectoprostatic fistula.

COUNT IV

CLAIM FOR NEGLIGENT WARNING 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.

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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 Todd William Waddle.

87.

The inadequate product warnings proximately caused Todd William Waddle's gel infiltration, ulceration of the rectal wall, and a rectoprostatic fistula.

88.

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

89.

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).

90.

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).

91.

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

92.

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

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93.

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

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

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

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

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

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

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

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

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

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

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

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

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

94.

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.

95.

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.

96.

As a direct and proximate result of Boston Scientific failing to adequately warn physicians, Todd William Waddle suffered gel infiltration, ulceration of the rectal wall, and a rectoprostatic fistula.

COUNT V

CLAIM FOR LOSS OF CONSORTIUM AGAINST BOSTON SCIENTIFIC CORPORATION

97.

Plaintiff Cheryl Nelson Waddle alleges and incorporates by reference herein each and every allegation set forth in Paragraphs 1 through 96 of this Complaint.

98.

Plaintiff Cheryl Nelson Waddle seeks compensation for the loss of companionship, affection, intimacy and household services caused by her husband's injuries.

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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,

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