Date Filed 10/14/2026 11:23 AM
Superior Court - Middlesex
Docket Number

COMMONWEALTH OF MASSACHUSETTS

MIDDLESEX, SS. **SUPERIOR COURT DEPARTMENT**
CIVIL ACTION NO.: 2681CV02731

DAVID RICHARD MACDONALD,

Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION,

Defendant.

RECEIVED
10/14/2026

COMPLAINT

Plaintiff, by and through counsel, files this Complaint against Boston Scientific Corporation as follows:

PARTIES, JURISDICTION AND VENUE

1.

Plaintiff David Richard Macdonald is a sixty-two-year-old male. Mr. Macdonald underwent placement of either SpaceOAR or SpaceOAR Vue on May 12, 2025 at Aultman Radiation Oncology in Canton, Ohio.

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.

4.

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

Date Filed 10/14/2026 11:23 AM
Superior Court - Middlesex
Docket Number

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 the device, including, but not limited to, documentation of an appropriate end user initial training

Date Filed 10/14/2026 11:23 AM
Superior Court - Middlesex
Docket Number

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.

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).

Date Filed 10/14/2026 11:23 AM
Superior Court - Middlesex
Docket Number

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.

30.

Date Filed 10/14/2026 11:23 AM
Superior Court - Middlesex
Docket Number

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.

36.

If a rectal wall is infiltrated with gel, adding radiation to the infiltrated rectal wall

Date Filed 10/14/2026 11:23 AM
Superior Court - Middlesex
Docket Number

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 August 22, 2024, David Richard Macdonald had an elevated Prostate-Specific Antigen (PSA) of 7.8 prompting biopsy for a suspicion of prostate cancer.

42.

A prostate needle biopsy was performed on January 27, 2025.

Date Filed 10/14/2026 11:23 AM
Superior Court - Middlesex
Docket Number

43.

Mr. Macdonald was diagnosed with organ-confined NCCN favorable intermediate risk prostate cancer, clinical T1, cN0 M0, Gleason 3+4 equal 7, PSA 7.8, prostate volume 16 cc.

44.

On April 7, 2025, Mr. Macdonald met with a radiation oncologist, Steven Olyejar, M.D. Dr. Olyejar recommended radiation treatment with stereotactic body radiation therapy (SBRT) in five sessions spread over two weeks.

45.

Dr. Olyehar recommended the use of SpaceOAR.

46.

On May 12, 2025, the SpaceOAR hydrogel was placed by Philip Schneider, M.D., a radiation oncologist, at Aultman Hospital.

47.

Mr. Macdonald's initial simulation set-up for the SBRT was done on May 19, 2025 at Aultman Hospital.

48.

The first of five fraction SBRT treatments were administered on June 4, 2025 at Aultman Hospital. The fifth and final fraction was completed on June 13, 2025.

49.

Mr. Macdonald presented to radiation oncology for office visits on July 14, 2025 and September 17, 2025 with reports of rectal pain.

50.

Date Filed 10/14/2026 11:23 AM
Superior Court - Middlesex
Docket Number

Daniel Sufficool, M.D., a radiation oncologist, noted on September 17, 2025 that the pain may be due to SpaceOAR.

51.

A CT of the pelvis on October 1, 2025 revealed a rectal wall ulceration at the site of the SpaceOAR.

52.

At a follow-up appointment on October 16, 2025, Dr. Sufficool diagnosed rectal wall infiltration and ulceration due to SpaceOAR.

53.

At a follow-up appointment on November 19, 2025, Mr. Macdonald continued to report severe rectal pain. Dr. Sufficool diagnosed rectal wall infiltration and ulceration due to SpaceOAR. Dr. Sufficool noted that Mr. Macdonald was unable to work due to the pain.

54.

At a follow-up appointment on December 24, 2025, Dr. Sufficool discussed his concern for sepsis and a rectal fistula and the need for imaging, wound care, and a surgical evaluation for possible diverting colostomy.

55.

Mr. Macdonald was admitted to Aultman Hospital on December 24, 2025 with complications from SpaceOAR. Mr. Macdonald was discharged December 28, 2025.

56.

On January 20, 2026, Mr. Macdonald was taken to the Cleveland Clinic Mercy Hospital emergency department with an altered mental status. Mr. Macdonald was discharged on January 26, 2026.

57.

On June 22, 2026, Mr. Macdonald returned to the Aultman Hospital emergency department with rectal pain.

58.

Mr. Macdonald returned to the Aultman Hospital emergency department again, five days later, on June 27, 2026. Mr. Macdonald reported urinating through his rectum.

59.

Mr. Macdonald returned to radiation oncology, Steven Eric Olyejar, M.D., at Aultman on July 15, 2026. Dr. Olyejar stated the Mr. Macdonald "unfortunately has developed a rectal prostatic cutaneous fistula now such that stool and urine exit out the fistula track in his perineum. He is seeing specialist in Akron to have a colostomy and a urostomy prior to a repair."

60.

Mr. Macdonald presented to the Cleveland Clinic on August 19, 2026 for evaluation of a rectourethral fistula with Christopher Lohr, M.D. ("Dr. Lohr"), a urologist. Dr. Lohr referred Mr. Macdonald to the Cleveland Clinic Hospital Main Campus.

61.

Mr. Macdonald was admitted to Cleveland Clinic Hospital main campus from September 18, 2026 to September 27, 2026 for worsening rectal pain.

62.

On September 19, 2026, a suprapubic catheter was placed.

63.

On September 21, 2026, Mr. Macdonald had a diverting colostomy.

Date Filed 10/14/2026 11:23 AM
Superior Court - Middlesex
Docket Number

64.

Mr. Macdonald continues to have significant rectal pain.

65.

Mr. Macdonald currently lives in a nursing facility due to complications from SpaceOAR.

66.

Mr. Macdonald has incurred medical expenses in excess of $500,000.00 due to rectal wall gel infiltration, rectal wall ulceration due to the gel infiltration, a 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

67.

Plaintiff David Richard Macdonald alleges and incorporates by reference herein each and every allegation set forth in Paragraphs 1 through 66 of this Complaint.

68.

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

69.

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

70.

Date Filed 10/14/2026 11:23 AM
Superior Court - Middlesex
Docket Number

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.

71.

The design defects in the SpaceOAR Vue directly and proximately caused David Richard Macdonald 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

72.

Plaintiff David Richard Macdonald alleges and incorporates by reference herein each and every allegation set forth in Paragraphs 1 through 71 of this Complaint.

73.

Defendant Boston Scientific Corporation is liable to Plaintiff because SpaceOAR Vue was defective due to inadequate product warnings which caused the product to be unreasonably dangerous to David Richard Macdonald.

74.

The inadequate product warnings proximately caused David Richard Macdonald's gel infiltration, ulceration of the rectal wall, rectourethral fistula, a colostomy with a colostomy bag

Date Filed 10/14/2026 11:23 AM
Superior Court - Middlesex
Docket Number

for fecal diversion, and a suprapubic catheter for urinary diversion.

75.

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

76.

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

77.

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

78.

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.

79.

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.

80.

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.

81.

As a direct and proximate result of Boston Scientific failing to adequately warn physicians, David Richard Macdonald 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

82.

Plaintiff David Richard Macdonald alleges and incorporates by reference herein each and every allegation set forth in Paragraphs 1 through 81 of this Complaint.

83.

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

84.

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.

85.

The negligent design of SpaceOAR Vue caused an unreasonable risk of injury to David Richard Macdonald.

86.

The negligent design of SpaceOAR Vue directly and proximately caused David Richard Macdonald 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

87.

Plaintiff David Richard Macdonald alleges and incorporates by reference herein each and every allegation set forth in Paragraphs 1 through 86 of this Complaint.

88.

Defendant Boston Scientific Corporation is liable to Plaintiff due to an inadequate warning which caused SpaceOAR Vue to be unreasonably dangerous to David Richard Macdonald.

89.

The inadequate product warnings proximately caused David Richard Macdonald'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.

90.

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

91.

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).

Date Filed 10/14/2026 11:23 AM
Superior Court - Middlesex
Docket Number

92.

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).

93.

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

94.

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

95.

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;

Date Filed 10/14/2026 11:23 AM
Superior Court - Middlesex
Docket Number

(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.

96.

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.

97.

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.

98.

As a direct and proximate result of Boston Scientific failing to adequately warn

physicians, David Richard Macdonald 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.

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.

Date Filed 10/14/2026 11:23 AM
Superior Court - Middlesex
Docket Number

This 14th day of October, 2026.

Plaintiffs,
By Their Attorney,

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