IN THE UNITED STATES DISTRICT COURT FOR THE
NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

Randy J. Africano and Diane Africano, *Plaintiffs,* v. Atrium Medical Corporation, A Delaware Corporation, *Defendant.*	Case No. 1:17-cv-7238

COMPLAINT

Plaintiffs Randy J. Africano and Diane Africano, for their Complaint against Defendant Atrium Medical Corporation ("hereinafter "Defendant" or "Atrium"), state as follows:

THE PARTIES, JURISDICTION AND VENUE

1. Plaintiffs are residents of the State of Illinois.

2. Defendant is a Delaware corporation with its principal office at 40 Continental Boulevard, Merrimack, New Hampshire 03054.

3. The Court has diversity jurisdiction under 28 U.S.C. §1332(a)(1), (2) because the matter in controversy exceeds $75,000 and is between citizens of different states, and the Defendant is a citizen of a foreign state.

4. The Court has personal jurisdiction over Defendant under Federal Rules of Civil Procedure Rule 4(k)(1)(A) and 735 ILCS 5/2-209(a)(1), (a)(2) because, among other bases for personal jurisdiction, the cause of action in this Complaint arises out of the commission of a tortious act in Illinois and Defendant does business in the state of Illinois by selling its products here. §2-209(b)(4), (c), (d).

5. Venue is proper in the Northern District of Illinois pursuant to 28 U.S.C. §1391(a)(2) and (a)(3) because a substantial part of the events and omissions giving rise to the claims in this Complaint occurred in this district, and because—for the reasons set forth immediately above—Defendant is also subject to personal jurisdiction in this district.

GENERAL ALLEGATIONS

6. At all times relevant, Defendant manufactured medical devices, including "ProLite" polypropylene surgical mesh (hereinafter "ProLite" or "ProLite mesh") at its facilities in Hudson, New Hampshire. ProLite mesh was used for hernia repair surgery. At all times relevant, Defendant sold ProLite mesh in the state of Illinois.

7. On or about February 3, 2015, The United States District Court for the District of New Hampshire entered a consent decree of permanent injunction (the "Decree") against Atrium and its affiliates to restrict the distribution of medical products manufactured at its facilities in Hudson, New Hampshire (the "Restricted Products") including ProLite mesh. A copy of the Decree is attached hereto, marked Exhibit A and incorporated herein by reference. The Decree was based upon a complaint (the "FDA Complaint") filed by the United States Food and Drug Administration (the "FDA") filed contemporaneously with the Decree, alleging that Atrium had violated FDA regulations designed to prevent the introduction of adulterated and misbranded medical devices into interstate commerce. A copy of the FDA Complaint is attached hereto, marked Exhibit B and incorporated herein by reference.

8. The FDA Complaint alleged, among others, that the FDA had issued a warning letter on October 11, 2012 (the "Warning Letter") detailing the results of an inspection of Atrium's facilities conducted in September 2012. A copy of the Warning Letter is attached hereto, marked Exhibit C and incorporated herein by reference. The Warning Letter recited numerous

violations, including violations of the most fundamental safety regulations ensuring sterilization of their devices. The FDA Complaint further alleged that inspections conducted in 2009, 2010, 2011 and July to October 2013 found essentially the same violations as recited in the Warning Letter.

9. The FDA Complaint prayed for an injunction against Atrium and its directors, officers and affiliates from introducing into interstate commerce medical devices that were adulterated within the meaning of 21 USC §351(h) in that the methods used in, and the facilitates and controls used for, their manufacture, packing, storage, and installation were not in conformity with the current good manufacturing practice ("CGMP") requirements for the devices and the relevant Quality System ("QS") regulations, and/or that were misbranded within the meaning of 21 USC § 352(t)(2) in that Atrium and its affiliates failed to furnish information or material respecting their devices, as set forth in 21 USC § 360(i) and the medical device reporting ("MDR") and correction and removals ("CR") regulations.

10. The QS regulations set forth current good manufacturing practice requirements for medical devices. The QS regulations govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage installation and servicing of all finished devices intended for human use. The regulations are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the federal Food, Drug and Cosmetic Act (the "FDCA"). A medical device that has been manufactured, packed, stored or installed in violation of the QS regulations is deemed to be adulterated.

11. The FDA Complaint prayed further for an injunction against Atrium and its officers, directors and affiliates restraining any of them from manufacturing, packing, labeling, holding or distributing medical devices from its Hudson, New Hampshire facility unless and until its

methods, facilities and controls used to manufacture, process, pack, label, hold, and distribute devices are established, operated and administered in conformance with MDR and QS regulations, acceptable to the FDA.

12. The Decree requires that Atrium's manufacturing facility in Hudson, New Hampshire, be shut down (with limited exceptions) until corrective actions described in the Decree are completed. Corrective actions include addressing the deficiencies previously identified by the FDA in the FDA Complaint and in its Warning Letter. Under the Decree, Atrium was to stop manufacturing and distributing the Restricted Devices from its Hudson facility until the Company made appropriate corrections to ensure compliance with the FDCA. As alleged above, ProLite mesh is one of the Restricted Products. A web page from Atrium's website listing ProLite mesh as one of the Restricted Products is attached hereto as Exhibit D and incorporated herein by reference. On information and belief, Atrium has not completed all the corrective actions required by the Decree at the Hudson, New Hampshire facility and has not resumed manufacture or distribution of ProLite mesh at that facility.

13. On or about December 10, 2013, Plaintiff Randy Africano underwent right-side inguinal hernia repair at Marshfield Clinic in Minocqua, Wisconsin. ProLite mesh was used in that procedure, in accordance with standard procedure and protocol, and in accordance with Atrium's specifications.

14. On or about September 28, 2015 Plaintiff underwent an ultrasound examination of the area surrounding the site of the surgery at Streeterville Open MRI LLC in Chicago, Illinois, resulting in diagnosis of a seroma, or collection of fluid at the site.

15. Plaintiff Randy Africano suffered continuously increasing pain associated with the seroma. Mr. Africano was told by his physicians that there was no satisfactory treatment for the

seroma, since draining the fluid could cause infection. The seroma continued to cause Mr. Africano pain, anxiety, stress, and a general deterioration in his health. Mr. Africano was in the midst of starting his sixth company, and the pain, anxiety, stress and general deterioration in his health severely and negatively affected his ability to perform his work.

16. On or about April 13, 2016, Mr. Africano's blood pressure became severely elevated and he admitted himself to Northwestern Memorial Hospital Emergency Department. He was kept for observation and then released. On or about July 27, 2016, Mr. Africano experienced severe pain in his upper right chest area and an enlargement and reddening of the seroma. He again admitted himself to the Northwestern Memorial Hospital Emergency Department. Plaintiff Randy Africano was immediately admitted to surgery, where Dr. Alexander Nagle drained the seroma and removed that part of the ProLite mesh that was not embedded in surrounding tissue. Mr. Africano was released from the hospital with an open, unsutured wound that had to be packed with gauze daily for ten weeks.

17. Since part of the mesh remains embedded in tissue, there is a continuing risk of infection, especially if the mesh becomes attached or has already become attached, to the colon. Plaintiff Randy Africano will require additional surgery to repair continuing damage and injury caused by the ProLite mesh that remains embedded in Plaintiff.

18. Mr. Africano had ProLite mesh—one of the Restricted Products—implanted less than 90 days after the FDA's July 9, 2013 through October 1, 2013 inspection of Atrium's manufacturing facility in which it documented numerous violations. On information and belief, the ProLite mesh implanted in Mr. Africano was manufactured at Atrium's facility during the period when the numerous violations were occurring.

COUNT I

Plaintiff Randy Africano Strict Liability Personal Injury

Plaintiff Randy Africano for Count I of his Complaint against Defendant states and alleges as follows:

19. Plaintiff Randy Africano hereby incorporates by reference paragraphs 6-18 above as if fully set forth herein, and further alleges as follows:

20. The ProLite mesh surgically implanted in Mr. Africano to repair his hernia was adulterated as that term is used in the US FDCA when it left Defendant's manufacturing facility. Atrium's failure to follow CGMP and QS regulations in its manufacture of its products at its Hudson, New Hampshire facility, including the ProLite mesh surgically implanted in Mr. Africano to repair his hernia, rendered the product adulterated, not suitable for surgical implantation in a patient for hernia repair, defective and unreasonably dangerous.

21. On information and belief, there were no warnings accompanying the sale of the ProLite mesh explaining that the ProLite mesh was adulterated; that Atrium failed to follow CGMP and QS when it manufactured the product; that Atrium had been cited by the FDA for failing to follow CGMP and QS in its manufacture of the ProLite mesh; or that any of the above circumstances would increase the risk of implanting the ProLite mesh to repair Mr. Africano's hernia.

22. Mr. Africano's doctors reasonably expected that the ProLite mesh would not be adulterated; that it would be manufactured in accordance with CGMP and QS; that it would be safe to implant to repair Plaintiff's hernia; and that it would be free from any defects in design and manufacture that would increase the risk of infection or damage to surrounding tissue. Because the product's intended use is for surgical implantation to repair a hernia, Mr. Africano's

and his doctors' expectations that the product would be free from defects in design and manufacture were high, and their expectations were reasonable.

23. The ProLite mesh surgically implanted to repair Mr. Africano's hernia was unreasonably dangerous, and was unreasonably dangerous when it left Atrium's manufacturing facility.

24. Plaintiff Randy Africano has sustained serious and permanent injuries as a direct result of the defective ProLite mesh surgically implanted to repair his hernia. Those injuries include but are not limited to infection; damage to surrounding tissue at the site of the implantation; damage to nerves at and around the site of the implantation; damage to tissue in which the ProLite mesh has become imbedded, including Mr. Africano's colon which, if not now symptomatic will likely become symptomatic, all of which required surgery to repair and mitigate. Post-surgery, Mr. Africano had an open wound 4-6 inches long that had to be dressed every day.

25. All the above has resulted in a decreased ability for Mr. Africano to enjoy a normal life. He continues to experience numbness, and can no longer engage in activities that he enjoyed before his injuries. His relationships with his family, including his wife, son and daughter have all been negatively impacted. Furthermore, since part of the mesh remains embedded in Mr. Africano, he will require additional surgery, causing further pain and suffering and risk of additional permanent injury. Because of the permanent damage to nerves at the site of the implantation and surgical extraction, Plaintiff Randy Africano will continue to experience numbness.

26. All the above injuries and damage are a direct and proximate result of the defective manufacture of the ProLite surgical mesh that rendered it unreasonably dangerous.

WHEREFORE, Plaintiff Randy Africano prays for judgment against the Defendant in an amount in excess of this Court's jurisdictional minimum, plus the costs of this action and whatever other relief this Honorable Court deems just and proper.

COUNT II

Plaintiff Randy Africano Negligence Personal Injury

Plaintiff Randy Africano for Count II of his Complaint against Defendant, states and alleges as follows:

27. Plaintiff Randy Africano hereby incorporates Paragraphs 6-26 above as if fully set forth herein and further states and alleges as follows:

28. Defendant had a duty to exercise the knowledge, skill and care that an expert in the manufacture of medical devices would use to make the ProLite mesh not only efficacious but safe for implantation for hernia repair, to provide adequate and effective warning of all significant health risks posed by its use, and to comply with FDCA rules and regulations pertaining to its manufacture, sale and distribution.

29. Defendant violated its duty in failing to comply with FDCA rules and regulations as set forth in the Decree. As a direct result of its violation of its duty as set forth in the Decree, the ProLite mesh used in Mr. Africano's surgery was adulterated and defective. Despite the fact that Defendant knew of the adulterated and defective nature of the ProLite mesh, it continued to sell and ship the ProLite mesh to hospitals and clinics, including Marshfield Clinic. Furthermore, Defendant violated its duty in failing to warn doctors—including Mr. Africano's doctors—of the defective and adulterated nature of ProLite mesh.

30. As a direct and proximate result of Defendant's negligence, Plaintiff Randy Africano has suffered and will continue to suffer the injuries, pain and damage described above.

WHEREFORE, Plaintiff Randy Africano prays for judgment against the Defendant in an amount in excess of this Court's jurisdictional minimum, plus the costs of this action and whatever other relief this Honorable Court deems just and proper.

COUNT III

Plaintiff Diane Africano Strict Liability Loss of Consortium

Plaintiff Diane Africano hereby alleges and incorporates herein by reference Paragraphs 6-30 above as if fully set forth herein and further states and alleges as follows:

31. Plaintiff Diane Africano is and at all relevant times has been the spouse of Plaintiff Randy Africano.

32. As a result of the personal injury suffered by Plaintiff Randy Africano, Plaintiff Diane Africano has been damaged in her marital relationship.

WHEREFORE, Plaintiff Diane Africano prays for judgment against the Defendant in an amount in excess of this Court's jurisdictional minimum, plus the costs of this action and whatever other relief this Honorable Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on all counts and as to all issues.

Dated: October 06, 2017

Respectfully submitted,

_/s/ James D. Benak
James D. Benak
ARDC No. 6205007
Attorney for Plaintiff
Tetzlaff Law Offices, LLC
227 West Monroe Street
Suite 3650
Chicago, IL 60606
(312) 574-1000 (T)
(312) 574-1001 (F)
(312) 497-0281 (M)