IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

PETER CIAPPA, and
TANYA CIAPPA
Plaintiff,

vs.

3M COMPANY,
a Delaware corporation, and
ARIZANT HEALTHCARE, INC.,
a Delaware corporation,

Defendants.

JURY TRIAL DEMANDED

Civil Action No.:

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs, PETER CIAPPA and TANYA CIAPPA by and through their undersigned attorneys sue Defendants 3M COMPANY and ARIZANT HEALTHCARE, INC., and file this Complaint, and alleges as follows:

I. JURISDICTION AND VENUE

1. This Court has jurisdiction pursuant to 28 U.S.C. § 1332, as complete diversity exists between Plaintiff and Defendants, and the amount in controversy exceeds $75,000.

2. Venue is proper within this district and division pursuant to 28 U.S.C. §1391, as a substantial number of the events, actions, or omissions giving rise to the Plaintiff's claims occurred in this district.

II. PARTIES

3. At all times relevant to this action, Plaintiff was a resident of Manorville, New York.

4. Defendant 3M is a Delaware corporation with its principal place of business located in Maplewood, Minnesota. 3M is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the Bair Hugger Forced Air Warming device (Bair Hugger).

5. Defendant Arizant is a corporation organized under the laws of the State of Delaware doing business in the State of Minnesota, and is a wholly owned subsidiary of Defendant 3M.

III. SUMMARY OF THE CASE

6. The Defendants, directly or through their agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed and sold the Bair Hugger.

7. As a result of the defective nature of the Bair Hugger, Plaintiff has suffered and may continue to suffer severe and permanent personal injuries.

8. On October 24, 2012, the Bair Hugger was used on Plaintiff during the course of his left hip replacement surgery.

9. Because the Bair Hugger was used, contaminants were introduced to Plaintiff's open surgical wound, thereafter resulting in infection, including but not limited to Cellulitis and Propionbacterium acnes.

10. Due to the infection, Plaintiff needed four additional surgical procedures to remove the implant and clean the infected area within sixteen months from the original implant surgery, and he continues to suffer limited mobility, requiring crutches to ambulate.

11. Plaintiff now suffers and will continue to suffer from permanent damages as a result of the Bair Hugger induced infection.

12. The Defendants concealed and continue to conceal their knowledge of the Bair Hugger's unreasonably dangerous risks from Plaintiff, other consumers, and the medical community.

13. The Defendants failed to conduct adequate and sufficient post-marketing surveillance after they began marketing, advertising, distributing and selling the Bair Hugger.

14. As a result of the Defendants' actions and inactions, Plaintiff was injured due to the use of the Bair Hugger, which has caused and will continue to cause Plaintiff's various injuries and damages. Accordingly, Plaintiff seeks compensatory damages.

IV. FACTUAL BACKGROUND

15. More than 50,000 Bair Hugger units are currently in use across the country.

16. The Bair Hugger consists of a portable heater/blower connected by a flexible hose to a disposable blanket that is positioned over (or in some cases under) surgical patients. The system warms patients during surgery by blowing hot air on a patient's exposed skin.

17. The hot air produced by Bair Hugger accumulates under the surgical drape covering the patient and escapes from under the surgical drape below the level of the surgical table or at the head end of the surgical table. This escaped air creates air flow currents that flow against the downward air flow of the operating room. As this warmed air rises, it deposits bacteria from the floor of the surgical room into the surgical site.

18. At some point between 2002 and 2009 the Defendants reduced the efficiency of the air filtration of Bair Hugger blowers. This action reduced the safety of such blowers.

19. As a result of these actions by the Defendants, the internal airflow paths of Bair Hugger blowers become contaminated with pathogens.

20. The pathogens contaminating the internal airflow paths of Bair Hugger blowers incubate and proliferate therein.

21. These pathogens are then expelled from the interior of the Bair Hugger blower by the outward airflow, travel through the hose into the disposable blanket and escape into the operating room.

22. The Defendants have been aware of the pathogenic contamination of the airflow paths of Bair Hugger blowers since at least 2009.

23. The Defendants have actively and aggressively marketed the Bair Hugger as safe in both general and orthopedic surgeries despite their knowledge to the contrary.

24. In a communication to the Food and Drug Administration ("FDA") in September 2000, Defendants represented that the Bair Hugger's filtration system meets HEPA ("High Efficiency Particulate Air") Standards. This statement was false at the time Defendants made it and it remains false today. To meet HEPA standards, an air filter must be capable of removing 99.97% of all particles 0.3 microns or larger. The filter of the Bair Hugger, which is marketed as HEPA compliant, is only capable of removing les that 65% of all such particles. When the Defendants made these representations, they had actual knowledge of their falsity.

25. In June of 1997, in a letter to the FDA, the Defendants admitted that "air blown intraoperatively across the surgical wound may result in airborne contamination." The Defendants addressed this flaw in their products by making further misrepresentations to the FDA when they stated that the risk of contamination by air flow is obviated because all "Bair Hugger Blankets designed for use in the operating room feature a tape barrier which prevent (sic) air from migrating toward the surgical site." That statement by the Defendants was and is patently false. A number of Bair Hugger blankets marketed as safe for use in surgeries do not utilize a taped edge at all. Instead, those blankets blow contaminated air directly toward the

surgical field. Also, the statement that the taped barrier would contain the contaminated air is false because it ignores the fact that the heated air from the Bair Hugger rises against the general downward airflow of the operating theatre. The presence of a tape edge does nothing to prevent the Bair Hugger from facilitating the movement of pathogens from the floor of the operating room to the surgical site. When the Defendants made these representations, they had actual knowledge of their falsity.

26. In their website, www.Facts.com (last visited July 17, 2015), the Defendants make the following misrepresentations:

a. Contamination mobilized by the convection currents generated by the Bair Hugger cannot reach the surgical site because "[a]ir velocity within the operating theatre is may times stronger than that of the forced-air warming blanket;

b. "The air emerging from the blanket is directed downward by the surgical drape and emerges under the operating room table and is drawn away through the laminar system's return air inlets;"

c. "It's been suggested that warm air rising above the Bair Hugger blanket could interfere with the downward laminar flow toward the surgical site. It should be noted that the Bair Hugger warming unit delivers less than one percent of the airflow of a laminar flow system and the momentum of the downward air is far greater than the upward momentum imparted to the air above the blanket."

27. The statements in the preceding paragraph are false and intentionally misleading. Through these statements, the Defendants disguise the fact that the issue is not the strength of the airflow in a laminar system but the heat of the air generated by the Bair Hugger. The cold air circulated with the operating room, having a higher density than the air heated by the Bair Hugger, falls to the floor which forces the contaminated air at the floor of the operating room, now warmed by the waste heat from the Bair Hugger, to rise into the sterile field and the surgical site. The heated air rises, it is not "drawn away" as the Defendants posit in their advertisement.

28. In an advertisement that appeared in multiple medical publications as early as 2010, available online at http://www.facts.com/_asset/zn062p/ (last visited Jul7 17, 2015), the Defendants made the following false and deliberately misleading claims:

> "While simple logic makes it clear that forced air warming has no impact on laminar conditions, science also supports this. A forced air warming blanket delivers less than one percent of the airflow of a laminar flow system and therefore is unable to affect laminar flow ventilation systems."

As published scientific research, before and after this statement, has demonstrated, this statement is untrue. The exhaust generated by the Bair Hugger creates convective airflow patterns that do disrupt the laminar flow of the operating theater.

29. In a communication that appeared in *Healthcare Purchasing News* in July of 2012, the Defendants' public relations and communications specialist Greta Deutsch stated "some conductive-warming manufacturers have alleged that forced-air warming increases bacterial contamination of operating rooms or interrupts laminar airflow. These accusations have no factual basis." Again, this statement ignores numerous published studies documenting the adverse effects the Bair Hugger has on laminar airflow.

30. The publication of numerous peer-reviewed studies documenting and revealing the critical safety shortcomings of the Bair Hugger should have prompted the Defendants to redesign or discontinue their product. Instead, those criticisms only caused the Defendants to amplify their efforts to champion the Bair Hugger. These publications include, but are not limited to, the following:

a. Albrecht M, Leaper D et al. Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room. *Am J Infect Control* 2011;39:321-8;

b. Leaper D et al. Forced-air warming: a source of airborne contamination in the operating room? *Orthopedic Rev*. 2009;1(2):e28;

c. McGovern et al. Forced-air warming and ultra-clean ventilation do not mix. *J Bone and Joint Surg-Br*. 2011;93(11):1537-1544;

d. Legg et al. Do forced air patient-warming devices disrupt unidirectional downward airflow? *J Bone and Joint Surg-Br*. 2012;94-B:254-6;

e. Belani et al. Patient warming excess heat: The effects on orthopedic operating room ventilation performance. *Anesthesia & Analgesia* 2012 (prepublication on-line) 2013;117(2):406-411; and

f. Dasari et al. Effect of forced air warming on the performance of operating theatre laminar flow ventilation. *Anaesthesia* 2012;67:244-249.

31. The effect of these misrepresentations was to mislead healthcare providers about the safety of the Bair Hugger for use in surgical procedures. The Defendants were aware of the falsity of their misrepresentations at the time those misrepresentations were authored.

32. Rather than alter the design of their product or warn physicians of the dangers associated with the Bair Hugger, as numerous studies confirm, the Defendants have chosen to do nothing but double down on their efforts to promote their defective product.

33. Plaintiffs' physicians' relied upon the above representations and advertisements to Plaintiff's detriment. Any reasonable and competent physician would not use a Bair Hugger in an orthopedic implant surgery if they were fully apprised of the dangers and risks associated with doing so. However, through misrepresentations to the public, the medical community, and the FDA, the Defendants actively concealed the infection causing propensity of the Bair Hugger in orthopedic implant surgeries.

34. As a result of the failure of the Defendants' Bair Hugger to maintain the sterility of the surgical area and the Defendants' wrongful conduct in designing, manufacturing, and marketing this defective product, Plaintiff and Plaintiff's physician were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this complaint, and that those risks were the direct and

proximate result of the Defendants' acts, omissions and misrepresentations.

V. CAUSES OF ACTION

NEGLIGENCE

35. Plaintiff restates the allegations set forth above as if fully rewritten herein.

36. The Defendants owed Plaintiff a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling the Bair Hugger.

37. The Defendants failed to exercise due care under the circumstances and therefore breached this duty by:

a. Failing to properly and thoroughly test Bair Hugger before releasing the device to market;

b. Failing to properly and thoroughly analyze the data resulting from the pre-market tests of the Bair Hugger;

c. Failing to conduct sufficient post-market testing and surveillance of the Bair Hugger;

d. Designing, manufacturing, marketing, advertising, distributing, and selling the Bair Hugger to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of the Bair Hugger and without proper instructions to avoid the harm which could foreseeably occur as a result of using the device;

e. Failing to exercise due care when advertising and promoting the Bair Hugger; and

f. Negligently continuing to manufacture, market, advertise, and distribute the Bair Hugger after Defendants knew or should have known of its adverse effects.

38. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff suffered infections including, but not limited to Cellulitis and Propionbacterium acnes, requiring four additional surgical procedures to clean the infected area and remove the hip implant. Consequently, Plaintiff has suffered damages and incurred and will

continue to incur medical expenses as a result of using the Bair Hugger. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting condition and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage earning capacity.

39. The Defendants' conduct as described above was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish the Defendants and deter them from similar conduct in the future.

VIOLATION OF NEW YORK CONSUMER PROTECTION LAWS

40. Plaintiff restates the allegations set forth above as if fully rewritten herein.

41. The Defendants have violated and continue to violate New York Consumer Protection statutes, NY GBS. §§ 349.

42. The Defendants are corporations who intentionally sell merchandise, including the Bair Hugger, to consumers, including consumers in Minnesota. The Defendants made false statements in their advertisement of the Bair Hugger, in violation of NY GBS. §§ 349.

43. In advertising the Bair Hugger through various means in New York, including but not limited to television, radio, internet, the products label, pamphlets and letters, the Defendants made material assertions, representations, or statements of fact which are untrue, deceptive, or misleading.

44. Similarly, the Defendants also acted with, used, or employed fraud, false pretense, false promise, misrepresentation, misleading statements or deceptive practices with

the intent that consumers, including Plaintiff, rely on said statements or actions in connection with the sale of the merchandise, in violation of NY GBS. §§ 349.

45. Defendants violated the New York consumer protection laws through, *inter alia*, the following:

a. Representing through statements and advertisements that the Bair Hugger has approval, characteristics, uses, or benefits that it does not have;

b. Representing through statements and advertisements that the Bair Hugger and its filtration system is of a particular standard, qualify, or grade when it differs materially from that representation;

c. Representing through statements and advertisement that the Bair Hugger has uses, benefits, or characteristics that have been otherwise proven incorrect;

d. Falsely stating, knowingly or with reason to know, that services or repairs are not needed.

46. As a direct and proximate result of the Defendants' actions, omissions, and misrepresentations, Plaintiff suffered infections including, but not limited to Cellulitis and Propionbacterium acnes, requiring four additional surgical procedures to clean the infected area and remove the hip implant. Consequently, Plaintiff has suffered damages and incurred and will continue to incur medical expenses as a result of using the Bair Hugger. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished qualify of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

47. The Defendants' conduct as described above was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish the Defendants and deter them from similar conduct in the future.

STRICY LIABILITY

48. Plaintiff restates the allegations set forth above as if fully rewritten herein.

49. The Defendants, or entities under their control, manufactured, sold, distributed, marketed or supplied the Bair Hugger in a defective and unreasonably dangerous condition to consumers, including Plaintiff.

50. Specifically, the Defendants failed to warn of the injuries suffered by Plaintiff as a result of using the Bair Hugger, and they introduced into the stream of commerce a defectively designed or manufactured product.

51. The Defendants designed, manufactured, sold distributed, supplied, marketed or promoted the Bair Hugger, which was expected to reach and did in fact reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by the Defendants.

52. Plaintiff used the Bair Hugger in a manner normally intended, recommended, promoted and marketed by the Defendants.

53. The Bair Hugger failed to perform safely when used by ordinary consumers, including Plaintiff, including when it was used as intended and in a reasonably foreseeable manner.

54. The propensity of the Bair Hugger's internal air flow passageways, including its non-HEPA compliant filter, to become contaminated with pathogens makes the Bair Hugger dangerous when used in the way it is ordinarily used and is dangerous to an extent beyond that

which would be contemplated by the ordinary consumer who purchased it, with the ordinary knowledge common to the community as to its characteristics.

A. Failure to Warn

55. Plaintiff restates the allegations set forth above as if fully rewritten herein.

56. Because the Defendants researched, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce the Bair Hugger and in doing so, directly advertised or marketed the product to the FDA, health care professionals, and consumers, or persons responsible for consumers, they had a duty to warn of the risks associated with the use of the Bair Hugger.

57. Defendants failed to adequately warn health care professionals and the public, including Plaintiff and his physician, of the true risks of the Bair Hugger, including that the Bair Hugger would circulate contaminated air in the operating room and that the vented heat from Bair Hugger would mobilize floor air contaminated with pathogens into the surgical site, causing deep joint infections, and requiring further treatment, including surgery or amputation.

58. Defendants failed to provide timely and reasonable warnings regarding the safety and efficacy of the Bair Hugger. Had they done so, proper warnings would have been heeded and no health care professional, including Plaintiff's physicians, would have used Bair Hugger and no patient, including Plaintiff, would have allowed use of the Bair Hugger.

59. The failure to provide timely and reasonable warnings, instructions, and information regarding the Bair Hugger to Plaintiff or his physician rendered the Bair Hugger unreasonably dangerous.

60. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff suffered infections including, but not limited to Cellulitis and Propionbacterium acnes, requiring four additional surgical procedures to clean the infected area

and remove the hip implant. Consequently, Plaintiff has suffered damages and incurred and will continue to incur medical expenses as a result of using the Bair Hugger. Plaintiff has also suffered and will continue to suffer diminished capacity of the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalizations, physician care, monitoring, treatment, medications and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage earning capacity.

61. The Defendants' conduct described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish the Defendants and deter them from similar conduct in the future.

B. Defective Design and Manufacture

62. Plaintiff restates the allegations set forth above as if fully rewritten here.

63. The design of the Bair Hugger or its component parts, make the Bair Hugger unreasonably dangerous, taking into consideration the utility of the device and the risk involved in its use.

64. At all times relevant to this action, an economically and technologically feasible safer alternative design existed, which in reasonable medical probability:

a. Would have prevented or significantly reduced the risk of Plaintiff's infection and subsequent amputation; and

b. Would not have impaired the utility of the device

65. Specifically, the Bair Hugger is defective in its design in that it is not reasonably fit, suitable or safe for its intended purpose or its foreseeable risks exceed the benefits

associated with its design.

66. The defective condition of the Bair Hugger rendered it unreasonably dangerous or not reasonably safe and the Bair Hugger was in this defective condition at the time it left the hands of the Defendants. The Bair Hugger was expected to and did reach Plaintiff and his physicians without substantial change in the condition in which it was designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied, and otherwise released into the stream of commerce.

67. Defendants knew or should have known of the danger associated with the use of the Bair Hugger, as well as the defective nature of the Bair Hugger, but have continued to design, manufacture, sell, distribute, market, promote, or supply the Bair Hugger so as to maximize sales and profits at the expense of the public health and safety, in conscious disregard of the foreseeable harm caused by Bair Hugger.

68. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff suffered infections including, but not limited to Cellulitis and Propionbacterium acnes, requiring four additional surgical procedures to clean the infected area and remove the hip implant. Consequently, Plaintiff has suffered damages and incurred and will continue to incur medical expenses as a result of using the Bair Hugger. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss wages and wage earning capacity.

69. The Defendants' conduct as described above was committed with knowing,

conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish the Defendants and deter them from similar conduct in the future.

BREACH OF EXPRESS WARRANTY

70. Plaintiff restates the allegations set forth above as if fully rewritten herein.

71. The Defendants expressly represented to Plaintiff and other consumers and the medical community that the Bair Hugger was safe and fit for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested.

72. The Bair Hugger does not conform to the Defendants' express representations because it is not safe, has numerous and serious side effects, and causes severe and permanent injury.

73. At all relevant times, the Bair Hugger did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

74. Plaintiff, other consumers, and the medical community reasonably relied upon the Defendants' express warranties for the Bair Hugger.

75. At all relevant times, the Bair Hugger was used on Plaintiff by his physicians for the purpose and in the manner intended by Defendants.

76. Plaintiff and Plaintiff's physicians, by the use of reasonable care, could not have discovered the breached warranty and realized its danger.

77. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff suffered infections including, but not limited to Cellulitis and Propionbacterium acnes, requiring four additional surgical procedures to clean the infected area and remove the hip implant. Consequently, Plaintiff has suffered damages and incurred and will

continue to incur medical expenses as a result of using the Bair Hugger. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss wages and wage earning capacity.

78. The Defendants' conduct as described above was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish the Defendants and deter them from similar conduct in the future.

BREACH OF IMPLIED WARRANTY

79. Plaintiff restates the allegations set forth above as if fully rewritten herein.

80. The Defendants designed, manufactured, distributed, advertised, promoted and sold the Bair Hugger.

81. At all relevant times, the Defendants knew of the use for which the Bair Hugger was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

82. The Defendants were aware that consumers, including Plaintiff, would use the Bair Hugger for treatment in conjunction with orthopedic surgical procedures.

83. Plaintiff, Plaintiff's physician and the medical community reasonably relied upon the judgment and sensibility of the Defendants to sell the Bair Hugger only if it was indeed of merchantable quality and safe and fir for its intended use.

84. The Defendants breached their implied warranty to consumers, including

Plaintiff; the Bair Hugger was not of merchantable quality or safe and fir for its intended use.

85. Consumers, including Plaintiff, Plaintiff's physician, and the medical community reasonably relied upon the Defendants implied warranty for the Bair Hugger FWA.

86. Plaintiff and Plaintiff's physician, by the use of reasonable care, would not have discovered the breached warranty and realized its danger.

87. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff suffered infections including, but not limited to Cellulitis and Propionbacterium acnes, requiring four additional surgical procedures to clean the infected area and remove the hip implant. Consequently, Plaintiff suffered damages and incurred and will continue to incur medical expenses as a result of using the Bair Hugger. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage earning capacity.

88. The Defendant's conduct as described above was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish the Defendants and deter them from similar conduct in the future.

NEGLIGENT MISREPRESENTATION

89. Plaintiff restates the allegations set forth above as if fully rewritten herein.

90. The Defendants made negligent misrepresentations with respect to the Bair Hugger including, but not limited to, the following particulars:

a. The Defendants represented through the labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that Bair Hugger has been tested and found to be safe and effective for the warming of patients during orthopedic implant surgery; and

b. The Defendants represented that Bair Hugger was safer than other patient warming systems.

91. Defendants did not exercise reasonable care or competence in obtaining or communicating the information to the public regarding the characteristics and qualities of the Bair Hugger.

92. Plaintiff and his physicians did, in fact, reasonably rely upon the representations.

93. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff suffered infections including, but not limited to Cellulitis and Propionbacterium acnes, requiring four additional surgical procedures to clean the infected area and remove the hip implant. Consequently, Plaintiff has suffered damages and incurred and will continue to incur medical expenses as a result of using the Bair Hugger. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage earning capacity.

94. The Defendants' conduct as described above was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to

punish the Defendants and deter them from similar conduct in the future.

FRAUDULENT MISREPRESENTATION

95. Plaintiff restates the allegations set forth above as if fully rewritten herein.

96. The Defendants made fraudulent misrepresentations with respect to the Bair Hugger including, but not limited to, the following particulars:

a. The Defendants represented through the labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that Bair Hugger has been tested and found to be safe and effective for the warming of patients during orthopedic implant surgery; and

b. The Defendants represented that Bair Hugger was safer than other patient warming systems.

97. Defendants knew that their representations were false, yet they willfully, wantonly, and recklessly disregarded their obligation to provide truthful representations regarding the safety and risks of Bair Hugger to consumers, including Plaintiff, and the medical community.

98. The representations were made by Defendants with the intent that doctors and patients, including Plaintiff, rely upon them.

99. The Defendants' representations were made with the intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale of Bair Hugger.

100. Plaintiff and his physicians did in fact rely upon the representations. In the absence of the Defendants' representations, the Bair Hugger would not be used in implantation surgeries such as the one at issue in this case.

101. The Defendants' fraudulent representations evidence their callous, reckless, and

willful indifference to the health, safety, and welfare of consumers, including Plaintiff.

102. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff suffered infections including, but not limited to Cellulitis and Propionbacterium acnes, requiring four additional surgical procedures to clean the infected area and remove the hip implant. Consequently, Plaintiff has suffered damaged and incurred and will continue to incur medical expenses as a result of using the Bair Hugger. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage earning capacity.

103. The Defendants' conduct as described above was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish the Defendants and deter them from similar conduct in the future.

FRAUDULENT CONCEALMENT

104. Plaintiff restates the allegations set forth above as if fully rewritten herein.

105. Defendants fraudulently concealed information with respect to the Bair Hugger including, but not limited to, the following particulars:

a. The Defendants represented through the labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that Bair Hugger was safe and fraudulently withheld and concealed information about the substantial risk of using Bair Hugger; and

b. The Defendants represented that Bair Hugger was safe and safer than other alternative systems and fraudulently concealed information that demonstrated that Bair Hugger was not safer than alternatives available on the market.

106. The Defendants had sole access to material facts concerning the dangers and unreasonable risks of the Bair Hugger.

107. The concealment of information by the Defendants about the risks of the Bair Hugger was intentional, and the representations made by Defendants were known by the Defendants to be false.

108. The concealment of information and the misrepresentations about Bair Hugger were made by the Defendants with the intent that doctors and patients, including Plaintiff and his doctors, rely upon them.

109. Plaintiff and his physicians relied upon the representations and were unaware of the substantial risks of the Bair Hugger which the Defendants concealed from the public, including Plaintiff and his physicians.

110. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff suffered infections including, but not limited to Cellulitis and Propionbacterium acnes, requiring four additional surgical procedures to clean the infected area and remove the hip implant. Consequently, Plaintiff has suffered damaged and incurred and will continue to incur medical expenses as a result of using the Bair Hugger. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and

suffering and loss of wages and wage earning capacity.

111. The Defendants' conduct as described above was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish the Defendants and deter them from similar conduct in the future.

LOSS OF CONSORTIUM

112. Plaintiff restates the allegations set forth above as if fully rewritten herein.

113. Plaintiff Tanya Ciappa is lawfully married to Peter Ciappa and, as such, is entitled to the services, society and companionship of his spouse.

114. As a direct and proximate result of the foregoing, Plaintiff Tanya Ciappa was deprived of the comfort and enjoyment of the services and society of her spouse, Plaintiff Peter Ciappa, has suffered and will continue to suffer economic loss, and has otherwise been emotionally and economically inured. Plaintiff Peter Ciappa's injuries and damages are permanent and will continue into the future.

115. The Defendants' conduct as described above was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish the Defendants and deter them from similar conduct in the future.

PUNITIVE DAMAGES

116. Plaintiff restates the allegations set forth above as if fully rewritten herein.

117. The Defendants' acts were willful and malicious in that the Defendants' conduct was carried on with a conscious disregard for the safety and rights of Plaintiff. The Defendants' unconscionable conduct thereby warrants an assessment of exemplary and punitive damages against the Defendants in an amount appropriate to punish the Defendants, and deter similar

conduct in the future.

118. Defendants' acts, misrepresentations or omissions, as described herein, were performed with a realization of the imminent threat posed by the Bair Hugger and were performed with reckless disregard or complete indifference to the probable result.

119. The Defendants had actual, subjective awareness of the risks involved in the above described acts or omissions, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of Plaintiff and the community at large.

120. Based on the facts stated herein, Plaintiff requests that punitive damages be awarded to Plaintiff from the Defendants.

WHEREFORE, Plaintiff prays for judgment against the Defendants, jointly and/or severally, as follows:

1. For general damages in an amount to be proven at the time of trial:
2. For special damages in an amount to be proven at the time of trial;
3. For exemplary and punitive damages in the amount to be proven at the time of trial, and sufficient to punish the Defendants or to deter the Defendants and others from repeating the injurious conduct alleged herein;
4. For pre-judgment and post-judgment interest on the above general and special damages;
5. For costs of this suit and attorneys' fees; and
6. All other relief that Plaintiff may be entitled to at equity or at law.

VI. DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all counts and issues so triable.

DATED this 25th day of November, 2015.

Respectfully submitted,

PARKER WAICHMAN LLP

By: _/s/ Daniel C. Burke

Daniel C. Burke, Esq.
Parker Waichman LLP
6 Harbor Park Drive
Port Washington, NY 11050
Telephone (516) 466-6500

Attorneys for Plaintiffs PETER CIAPPA AND TANYA CIAPPA

JS 44 (Rev. 1/2013)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Peter Ciappa and Tanya Ciappa

(b) County of Residence of First Listed Plaintiff Suffolk
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Parker Waichman LLP
Daniel C. Burke, Esq.
6 Harbor Park Drive Port Washington, NY 11050 (516) 466-6500

DEFENDANTS

3M Company, and Arizant Healthcare, Inc.,

County of Residence of First Listed Defendant Ramsey County
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ❒ 1 U.S. Government Plaintiff
- ❒ 3 Federal Question *(U.S. Government Not a Party)*
- ❒ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	❒ 1	Incorporated *or* Principal Place of Business In This State	❒ 4	❒ 4
Citizen of Another State	❒ 2	❒ 2	Incorporated *and* Principal Place of Business In Another State	❒ 5	☒ 5
Citizen or Subject of a Foreign Country	❒ 3	❒ 3	Foreign Nation	❒ 6	❒ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ❒ 110 Insurance
- ❒ 120 Marine
- ❒ 130 Miller Act
- ❒ 140 Negotiable Instrument
- ❒ 150 Recovery of Overpayment & Enforcement of Judgment
- ❒ 151 Medicare Act
- ❒ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ❒ 153 Recovery of Overpayment of Veteran's Benefits
- ❒ 160 Stockholders' Suits
- ❒ 190 Other Contract
- ❒ 195 Contract Product Liability
- ❒ 196 Franchise

REAL PROPERTY
- ❒ 210 Land Condemnation
- ❒ 220 Foreclosure
- ❒ 230 Rent Lease & Ejectment
- ❒ 240 Torts to Land
- ❒ 245 Tort Product Liability
- ❒ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ❒ 310 Airplane
- ❒ 315 Airplane Product Liability
- ❒ 320 Assault, Libel & Slander
- ❒ 330 Federal Employers' Liability
- ❒ 340 Marine
- ❒ 345 Marine Product Liability
- ❒ 350 Motor Vehicle
- ❒ 355 Motor Vehicle Product Liability
- ❒ 360 Other Personal Injury
- ❒ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ❒ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ❒ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ❒ 370 Other Fraud
- ❒ 371 Truth in Lending
- ❒ 380 Other Personal Property Damage
- ❒ 385 Property Damage Product Liability

CIVIL RIGHTS
- ❒ 440 Other Civil Rights
- ❒ 441 Voting
- ❒ 442 Employment
- ❒ 443 Housing/ Accommodations
- ❒ 445 Amer. w/Disabilities - Employment
- ❒ 446 Amer. w/Disabilities - Other
- ❒ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ❒ 463 Alien Detainee
- ❒ 510 Motions to Vacate Sentence
- ❒ 530 General
- ❒ 535 Death Penalty

Other:
- ❒ 540 Mandamus & Other
- ❒ 550 Civil Rights
- ❒ 555 Prison Condition
- ❒ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ❒ 625 Drug Related Seizure of Property 21 USC 881
- ❒ 690 Other

LABOR
- ❒ 710 Fair Labor Standards Act
- ❒ 720 Labor/Management Relations
- ❒ 740 Railway Labor Act
- ❒ 751 Family and Medical Leave Act
- ❒ 790 Other Labor Litigation
- ❒ 791 Employee Retirement Income Security Act

IMMIGRATION
- ❒ 462 Naturalization Application
- ❒ 465 Other Immigration Actions

BANKRUPTCY
- ❒ 422 Appeal 28 USC 158
- ❒ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ❒ 820 Copyrights
- ❒ 830 Patent
- ❒ 840 Trademark

SOCIAL SECURITY
- ❒ 861 HIA (1395ff)
- ❒ 862 Black Lung (923)
- ❒ 863 DIWC/DIWW (405(g))
- ❒ 864 SSID Title XVI
- ❒ 865 RSI (405(g))

FEDERAL TAX SUITS
- ❒ 870 Taxes (U.S. Plaintiff or Defendant)
- ❒ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ❒ 375 False Claims Act
- ❒ 400 State Reapportionment
- ❒ 410 Antitrust
- ❒ 430 Banks and Banking
- ❒ 450 Commerce
- ❒ 460 Deportation
- ❒ 470 Racketeer Influenced and Corrupt Organizations
- ❒ 480 Consumer Credit
- ❒ 490 Cable/Sat TV
- ❒ 850 Securities/Commodities/ Exchange
- ❒ 890 Other Statutory Actions
- ❒ 891 Agricultural Acts
- ❒ 893 Environmental Matters
- ❒ 895 Freedom of Information Act
- ❒ 896 Arbitration
- ❒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ❒ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ❒ 2 Removed from State Court ❒ 3 Remanded from Appellate Court ❒ 4 Reinstated or Reopened ❒ 5 Transferred from Another District *(specify)* ❒ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. § 1332

Brief description of cause:

VII. REQUESTED IN COMPLAINT:

❒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ❒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
11/25/2015

SIGNATURE OF ATTORNEY OF RECORD
/s/ Daniel C. Burke, Esq.

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

CERTIFICATION OF ARBITRATION ELIGIBILITY

Local Arbitration Rule 83.10 provides that with certain exceptions, actions seeking money damages only in an amount not in excess of $150,000, exclusive of interest and costs, are eligible for compulsory arbitration. The amount of damages is presumed to be below the threshold amount unless a certification to the contrary is filed.

I, _____, counsel for _____, do hereby certify that the above captioned civil action is ineligible for compulsory arbitration for the following reason(s):

☐ monetary damages sought are in excess of $150,000, exclusive of interest and costs,

☐ the complaint seeks injunctive relief,

☐ the matter is otherwise ineligible for the following reason

DISCLOSURE STATEMENT - FEDERAL RULES CIVIL PROCEDURE 7.1

Identify any parent corporation and any publicly held corporation that owns 10% or more or its stocks:

RELATED CASE STATEMENT (Section VIII on the Front of this Form)

Please list all cases that are arguably related pursuant to Division of Business Rule 50.3.1 in Section VIII on the front of this form. Rule 50.3.1 (a) provides that "A civil case is "related" to another civil case for purposes of this guideline when, because of the similarity of facts and legal issues or because the cases arise from the same transactions or events, a substantial saving of judicial resources is likely to result from assigning both cases to the same judge and magistrate judge." Rule 50.3.1 (b) provides that " A civil case shall not be deemed "related" to another civil case merely because the civil case: (A) involves identical legal issues, or (B) involves the same parties." Rule 50.3.1 (c) further provides that "Presumptively, and subject to the power of a judge to determine otherwise pursuant to paragraph (d), civil cases shall not be deemed to be "related" unless both cases are still pending before the court."

NY-E DIVISION OF BUSINESS RULE 50.1(d)(2)

1.) Is the civil action being filed in the Eastern District removed from a New York State Court located in Nassau or Suffolk County: No

2.) If you answered "no" above:
a) Did the events or omissions giving rise to the claim or claims, or a substantial part thereof, occur in Nassau or Suffolk County? Yes

b) Did the events or omissions giving rise to the claim or claims, or a substantial part thereof, occur in the Eastern District? Yes

If your answer to question 2 (b) is "No," does the defendant (or a majority of the defendants, if there is more than one) reside in Nassau or Suffolk County, or, in an interpleader action, does the claimant (or a majority of the claimants, if there is more than one) reside in Nassau or Suffolk County?_____

(Note: A corporation shall be considered a resident of the County in which it has the most significant contacts).

BAR ADMISSION

I am currently admitted in the Eastern District of New York and currently a member in good standing of the bar of this court.

☒ Yes ☐ No

Are you currently the subject of any disciplinary action (s) in this or any other state or federal court?

☐ Yes (If yes, please explain) ☒ No

I certify the accuracy of all information provided above.

Signature: /s/ Daniel C. Burke