IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

IN RE: BAIR HUGGER FORCED AIR WARMING DEVICES PRODUCTS LIABILITY LITIGATION

MDL No.: 15-2666 (JNE/FLN)

This document relates to:

Bobby Thomas,
Plaintiff,
vs.

Civil Action No.:

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

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff, Bobby Thomas, by and through Plaintiff's undersigned attorneys, brings this Complaint against Defendants 3M COMPANY and ARIZANT HEALTHCARE, INC., (hereinafter referred collectively as "Defendant"), and alleges as follows:

This is an action for damages relating to Defendant's design, development, testing, assembling, manufacturing, packaging, promoting, marketing, distribution, supplying, and/or selling the defective device sold under the trade names of Bair Hugger Forced Air Warming device (hereinafter "Bair Hugger", or "Defective Device").

I. PARTIES

1. At all times relevant to this action, Plaintiff was a resident and citizen of the city of Bunnlevel, the county of Harnett, and the state of North Carolina.

2. Defendant 3M is a corporation organized and existing under the laws of the State of Delaware, 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.

3. Defendant Arizant Healthcare is a corporation organized and existing under the laws of the State of Delaware, Arizant Healthcare conducts business throughout the United States, including the State of Minnesota, and is a wholly owned subsidiary of Defendant 3M.

II. JURISDICTION AND VENUE

4. This Court has jurisdiction pursuant to 28 U.S.C. § 1332, as complete diversity exists between Plaintiff and Defendant, and the amount in controversy exceeds $75,000. Defendant is subject to *in personam* jurisdiction in this court, and venue is proper within this district 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. At all times relevant to this matter, Defendant 3M Company ("3M") and ARIZANT HEALTHCARE, INC ("Arizant") (collectively "Defendant") conducted substantial business in this district. Defendant did (and does) business within the state of Minnesota and has had substantial, continuous, and systematic contacts with the state of Minnesota, has consented to jurisdiction in the state of Minnesota, and/or committed a tort in whole or in part in the state of Minnesota, and many other states, against thousands of Plaintiffs, including Plaintiff herein, as more fully set forth below. On information and belief, Defendant also marketed, advertised, and sold the defective devices in the District of Minnesota, and many other states, made material omissions and representations in each of these districts, and breached warranties in these districts.

III. SUMMARY OF THE CASE

5. The Defendant, directly or through its agents, apparent agents, servants, or employees, designed, manufactured, marketed, advertised, distributed, and sold the Bair

Hugger.

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

7. In April 2013, the Bair Hugger was used on Plaintiff during the course of Plaintiff's left hip replacement surgery.

8. Because the Bair Hugger was used, contaminants were introduced to Plaintiff's open surgical wound, resulting in an infection.

9. Due to the infection, Plaintiff needed multiple additional surgical procedures to remove portions of the hip implant and clean the infected area within a few weeks from the original implant surgery, and Plaintiff continues to suffer substantial damages, including but not limited to impaired mobility.

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

11. The Defendant concealed and continues to conceal its knowledge of the Bair Hugger's unreasonably dangerous risks from Plaintiff, other consumers, and the medical community.

12. The Defendant failed to conduct adequate and sufficient post-marketing surveillance after it began marketing, advertising, distributing, and selling the Bair Hugger.

13. As a result of the Defendant's 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

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

15. 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.

16. 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.

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

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

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

20. 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.

21. The Defendant has been aware of the pathogenic contamination of the airflow paths of Bair Hugger blowers since at least 2009.

22. The Defendant has actively and aggressively marketed the Bair Hugger as safe in both general and orthopedic surgeries despite its knowledge to the contrary.

23. In a communication to the Food and Drug Administration ("FDA") in September 2000, Defendant represented that the Bair Hugger's filtration system meets HEPA ("High Efficiency Particulate Air") Standards. This statement was false at the time Defendant 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 less than 65% of all such particles. When the Defendant made these representations, it had actual knowledge of their falsity.

24. In June of 1997, in a letter to the FDA, the Defendant admitted that "air blown intraoperatively across the surgical wound may result in airborne contamination." The Defendant addressed this flaw in its products by making further misrepresentations to the FDA when it 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 Defendant 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 Defendant made these representations, it had actual knowledge of their falsity.

25. On its website, www.fawfacts.com/laminar_airflow/ (last visited January 20, 2016), the Defendant makes 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 room is many times stronger than that of a 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."

26. The statements in the preceding paragraph are false and intentionally misleading. Through these statements, the Defendant disguised the fact that the issue is not the strength of the airflow in a unidirectional system but the heat of the air generated by the Bair Hugger. The cold air circulated within 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, and is not "drawn away" as the Defendant falsely claims in advertisements.

27. In an advertisement that appeared in multiple medical publications as early as 2010, available online at http://www.fawfacts.com/_asset/zn062p/AJIC.pdf (last visited July 17, 2015), the Defendant 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 which disrupt the unidirectional flow of the operating theater.

28. In a communication that appeared in *Healthcare Purchasing News* in July of 2012, the Defendant's 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 unidirectional airflow.

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

a. Albrecht M, et al. Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room. *Am J Infect Control* 2010;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, P.D., et al. Forced-air warming and ultra-clean ventilation do not mix. *J Bone and Joint Surg-Br.* 2011;93-B(11):1537-1544;

d. Legg, A. 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, K., 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;

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

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

31. Rather than alter the design of the product or warn physicians of the dangers associated with the Bair Hugger, as numerous studies confirm, the Defendant has chosen to "double down" on efforts to promote the defective product.

32. Plaintiff's 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 Defendant actively and knowingly concealed the propensity of these devices to cause infection in orthopedic implant surgeries.

33. As a result of the failure of the Defendant's Bair Hugger to maintain the sterility of the surgical area and the Defendant's wrongful conduct in designing, manufacturing, and marketing this defective product, Plaintiff and Plaintiff's physicians 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 Defendant's acts, omissions, and misrepresentations.

V. CAUSES OF ACTION

COUNT ONE - NEGLIGENCE

34. Plaintiff restates the allegations set forth above as if fully rewritten herein and further alleges as follows:

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

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

a. Failing to properly and thoroughly test the 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 Defendant knew or should have known of its adverse effects.

37. As a direct and proximate result of the Defendant's actions, omissions, and misrepresentations, Plaintiff suffered an infection, requiring additional surgical procedures to clean the infected area and remove portions of 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.

38. 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. Defendant's conduct warrants, if allowed by the Court upon motion, an award of punitive damages against Defendant in an amount appropriate to punish the Defendant and deter it from similar conduct in the future.

COUNT TWO - VIOLATION OF MINNESOTA'S CONSUMER PROTECTION AND DECEPTIVE TRADE PRACTICES LAWS

39. Plaintiff restates the allegations set forth above as if fully rewritten herein and further alleges as follows:

40. The Defendant has violated and continues to violate Minnesota Consumer Protection statutes, Minn. Stat. §§ 325F.67; 325F.69, and Minnesota's Deceptive Trade Practices statutes, Minn. Stat. §§ 325D.44.

41. The Defendant is a corporation which intentionally sells merchandise, including the Bair Hugger, to consumers, including consumers in Minnesota. The Defendant made false statements in advertisements for the Bair Hugger, in violation of Minn. Stat. § 325F.67.

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

43. Similarly, the Defendant 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 Minn. Stat. § 325F.69.

44. Defendant violated the Minnesota 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, quality, 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.

45. As a direct and proximate result of the Defendant's actions, omissions, and misrepresentations, Plaintiff suffered an infection, requiring additional surgical procedures to clean the infected area and remove portions of 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.

46. 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. Defendant's conduct warrants, if allowed by the Court upon motion, an award of punitive damages against Defendant in an amount appropriate to punish the Defendant and deter it from similar conduct in the future.

COUNT THREE - STRICT LIABILITY

47. Plaintiff restates the allegations set forth above as if fully rewritten herein and further alleges as follows:

48. The Defendant, or entities under its control, manufactured, sold, distributed,

marketed, or supplied the Bair Hugger in a defective and unreasonably dangerous condition to consumers, including Plaintiff.

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

50. The Defendant 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 Defendant.

51. Plaintiff and Plaintiff's physicians used the Bair Hugger in a manner normally intended, recommended, promoted, and marketed by the Defendant.

52. 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.

53. 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 unreasonably 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. Strict Liability - Failure to Warn

54. Plaintiff restates the allegations set forth above as if fully rewritten herein and further alleges as follows:

55. Because the Defendant 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, it had a duty to warn of the risks associated with the use of the Bair Hugger.

56. Defendant failed to adequately warn health care professionals and the public, including Plaintiff and Plaintiff's 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.

57. Defendant failed to provide timely and reasonable warnings regarding the safety and efficacy of the Bair Hugger. Had it 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.

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

59. As a direct and proximate result of the Defendant's actions, omissions, and misrepresentations, Plaintiff suffered an infection, requiring additional surgical procedures to clean the infected area and remove portions of 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.

60. The Defendant's 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. Defendant's conduct warrants, if allowed by the Court upon motion, an award of punitive damages against Defendant in an amount appropriate to punish the Defendant and deter it from similar conduct in the future.

B. Strict Liability - Defective Design and Manufacture

61. Plaintiff restates the allegations set forth above as if fully rewritten herein and further alleges as follows:

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

63. 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 injuries (including additional surgical procedures to clean the infected area and remove portions of the implant);and

b. would not have impaired the utility of the device

64. 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.

65. 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 Defendant. The Bair Hugger was expected to and did reach Plaintiff and Plaintiff's

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.

66. Defendant 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 has 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.

67. As a direct and proximate result of the Defendant's actions, omissions, and misrepresentations, Plaintiff suffered an infection, requiring additional surgical procedures to clean the infected area and remove portions of 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.

68. 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. Defendant's conduct warrants, if allowed by the Court upon motion, an award of punitive damages against Defendant in an amount appropriate to punish the Defendant and deter it from similar conduct in the future.

COUNT FOUR - BREACH OF EXPRESS WARRANTY

69. Plaintiff restates the allegations set forth above as if fully rewritten herein and further alleges as follows:

70. The Defendant 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.

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

72. 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.

73. Plaintiff, other consumers, and the medical community reasonably relied upon the Defendant's express warranties for the Bair Hugger.

74. At all relevant times, the Bair Hugger was used on Plaintiff by Plaintiff's physicians for the purpose and in the manner intended by Defendant.

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

76. As a direct and proximate result of the Defendant's actions, omissions, and misrepresentations, Plaintiff suffered an infection, requiring additional surgical procedures to clean the infected area and remove portions of 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.

77. 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. Defendant's conduct warrants, if allowed by the Court upon motion, an award of punitive damages against Defendant in an amount appropriate to punish the Defendant and deter it from similar conduct in the future.

COUNT FIVE - BREACH OF IMPLIED WARRANTY

78. Plaintiff restates the allegations set forth above as if fully rewritten herein and further alleges as follows:

79. The Defendant designed, manufactured, distributed, advertised, promoted, and sold the Bair Hugger.

80. At all relevant times, the Defendant 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.

81. The Defendant was aware that consumers, including Plaintiff, would use the Bair Hugger for treatment in conjunction with orthopedic surgical procedures.

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

83. The Defendant breached an implied warranty to consumers, including Plaintiff; the Bair Hugger was not of merchantable quality or safe and fit for its intended use.

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

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

86. As a direct and proximate result of the Defendant's actions, omissions, and misrepresentations, Plaintiff suffered an infection, requiring additional surgical procedures to clean the infected area and remove portions of 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.

87. 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. Defendant's conduct warrants, if allowed by the Court upon motion, an award of punitive damages against Defendant in an amount appropriate to punish the Defendant and deter it from similar conduct in the future.

COUNT SIX - NEGLIGENT MISREPRESENTATION

88. Plaintiff restates the allegations set forth above as if fully rewritten herein and further alleges as follows:

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

a. The Defendant 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 Defendant represented the Bair Hugger was safer than other patient warming systems.

90. Defendant 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.

91. Plaintiff and Plaintiff's physicians did, in fact, reasonably rely upon the representations.

92. As a direct and proximate result of the Defendant's actions, omissions, and misrepresentations, Plaintiff suffered an infection, requiring additional surgical procedures to clean the infected area and remove portions of 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.

93. 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. Defendant's conduct warrants, if allowed by the

Court upon motion, an award of punitive damages against Defendant in an amount appropriate to punish the Defendant and deter it from similar conduct in the future.

COUNT SEVEN - FRAUDULENT MISREPRESENTATION

94. Plaintiff restates the allegations set forth above as if fully rewritten herein and further alleges as follows:

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

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

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

96. Defendant knew that these representations were false, yet it willfully, wantonly, and recklessly disregarded its obligation to provide truthful representations regarding the safety and risks of Bair Hugger to consumers, including Plaintiff, and the medical community.

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

98. The Defendant's 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.

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

100. The Defendant's fraudulent representations evidence a callous, reckless, and

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

101. As a direct and proximate result of the Defendant's actions, omissions, and misrepresentations, Plaintiff suffered an infection, requiring additional surgical procedures to clean the infected area and remove portions of 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.

102. 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. Defendant's conduct warrants, if allowed by the Court upon motion, an award of punitive damages against Defendant in an amount appropriate to punish the Defendant and deter it from similar conduct in the future.

COUNTH EIGHT - FRAUDULENT CONCEALMENT

103. Plaintiff restates the allegations set forth above as if fully rewritten herein and further alleges as follows:

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

a. The Defendant represented through the labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that the Bair Hugger was safe and fraudulently withheld and

concealed information about the substantial risk of using Bair Hugger; and

b. The Defendant 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.

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

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

107. The concealment of information and the misrepresentations about Bair Hugger were made by the Defendant with the intent that doctors and patients, including Plaintiff and Plaintiff's physicians, rely upon them.

108. Plaintiff and Plaintiff's physicians relied upon the representations and were unaware of the substantial risks of the Bair Hugger which the Defendant concealed from the public, including Plaintiff and Plaintiff's physicians.

109. As a direct and proximate result of the Defendant's actions, omissions, and misrepresentations, Plaintiff suffered an infection, requiring additional surgical procedures to clean the infected area and remove portions 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.

110. 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. Defendant's conduct warrants, if allowed by the Court upon motion, an award of punitive damages against Defendant in an amount appropriate to punish the Defendant and deter it from similar conduct in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against the Defendant as follows:

1. For an award of compensatory damages in excess of Seventy-Five Thousand Dollars ($75,000.00);
2. If allowed by the Court upon motion, an award of punitive damages in the amount to be proven at the time of trial, and sufficient to punish the Defendant or to deter the Defendant and others from repeating the injurious conduct alleged herein;
3. For pre-judgment and post-judgment interest on the above general and special damages;
4. For costs of this suit and attorneys' fees; and
5. For all other relief that Plaintiff may be entitled to at equity or at law.
6. For such further and other relief that this Court deems just and equitable.

DEMAND FOR JURY TRIAL

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

Respectfully Submitted,

DATED this 13th day of April, 2016.

KIRTLAND & PACKARD LLP

/s/ Behram V. Parekh
Michael Louis Kelly (CASBN 82063)
mlk@kirtlandpackard.com

Behram V. Parekh (CASBN 180361)
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El Segundo, California 90245
Telephone: (310) 536-1000
Facsimile: (310) 536-1001

Attorneys for Plaintiff

Attachment A

List of United States Federal Courts to which Counsel for Plaintiff is Admitted

Supreme Court of the United States
Supreme Court of the State of California
United States Court of Appeals for the Second Circuit
United States Court of Appeals for the Ninth Circuit
United States Court of Appeals for the Tenth Circuit
United States District Court, Central District of California
United States District Court, Eastern District of California
United States District Court, Northern District of California
United States District Court, Southern District of California
United States District Court, District of Colorado
United States District Court, Western District of Michigan
United States District Court, Northern District of Oklahoma

I hereby certify that I am admitted to the preceding United States District Court and that I have not been disbarred or suspended from practice before any of these Courts or any other United States District Court.

Dated this 13th day of April, 2016.

/s/ Behram V. Parekh
Behram V. Parekh (CA #180361)
bvp@kirtlandpackard.com
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JS 44 (Rev. 12/12)

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
BOBBY THOMAS, an individual

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
KIRTLAND & PACKARD, LLP, 2041 ROSECRANS AVE, THIRD FLOOR, EL SEGUNDO, CA 90245, 310-536-1000

DEFENDANTS
3M COMPANY, a Delaware Corporation and ARIZANT HEALTHCARE, INC., a Delaware Corporation

County of Residence of First Listed Defendant NEW CASTLE, DE
(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; FRAUD
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 Joan N. Ericksen DOCKET NUMBER MDL No. 15-2666(JNE/FLN)

DATE 04/13/2016

SIGNATURE OF ATTORNEY OF RECORD /s/ Behram V. Parekh

FOR OFFICE USE ONLY

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

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading 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. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. Origin. Place an "X" in one of the six boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.