

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

MANUEL G. GRIEGO,)	
)	CASE NO. _____
Plaintiff,)	
)	
v.)	
)	
3M COMPANY, and ARIZANT)	COMPLAINT AND
HEALTHCARE, INC.,)	JURY DEMAND
jointly and individually,)	
)	
Defendants.)	
)	

Plaintiff, by and through undersigned counsel, brings the following Complaint against Defendants and alleges as follows:

INTRODUCTION

1. The Bair Hugger Temperature Management System forced air warming device (“Bair Hugger”) was developed by Augustine Medical, Inc., the corporate predecessor to Defendant Arizant Healthcare, Inc. (“Arizant”), in the 1980s. When Augustine medical reorganized in 2003, the division that retained the Bair Hugger became Defendant Arizant.

2. In 2010, Defendant 3M Company (“3M”) purchased Arizant including the rights to its Bair Hugger product line.

3. The Bair Hugger is a product used in surgical procedures that is intended to keep the patient warm during the operation. This is accomplished by blowing warm, forced air over the patient.

4. The Bair Hugger temperature management system consists of a portable forced-air temperature management unit and a disposable Bair Hugger forced-air blanket. All models

are equipped with a flexible hose that blows hot air into the blanket and over the patient's exposed skin.

5. Bair Huggers come in 25 different styles, some covering only a portion of the patient's body, others covering the patient's entire body, while still others are used under the patient's body in order to allow the surgeon full access to the patient.

6. Bair Huggers are marketed as being able to "meet your everyday and specialized patient warming needs-from pediatric to geriatric, from brief outpatient procedures to long complex procedures." In short, Bair Huggers are advertised as being suitable for use by absolutely everyone. This is even reflected in Bair Hugger's marketing slogan: Everyone Deserves a Hugg™.

7. Since their introduction in the market, use of Bair Hugger blankets has become pervasive, as a Bair Hugger is currently used in surgical procedures in more than 80 percent of hospitals across the country. As of 2012, nine of the top 10 orthopedic hospitals as rated by U.S. News and 13 of the top 15 used Bair Hugger warming products during their surgeries.

8. However, despite the continued representations of Defendants, the Bair Hugger is neither safe nor effective for use in general or orthopedic surgeries.

9. The Bair Hugger produces hot air that builds up in areas around the patient, particularly under the surgical drape covering the patient. The air escapes either from under the surgical drape below the level of the surgical table or at the head end of the surgical table. When the air escapes, a current of air is formed that is forced downward toward the floor of the operating room.

10. When this hot air from the Bair Hugger escapes and is pushed down to the floor, the air picks up bacteria and other pathogens from the floor. When the still-warmer-than-the-

operating-room-temperature air begins to rise after leaving the air current caused by the Bair Hugger, the bacteria and other pathogens picked up from the floor of the operating room are deposited into the surgical site.

11. These bacteria can and do lead to significant and preventable infections for patients, including Plaintiff.

12. Upon information and belief, Defendants have known of the danger of infections present in its Bair Hugger system for many years, and have continued to misrepresent the safety of the Bair Hugger in advertisements, statements to healthcare providers, and in submissions to the FDA.

13. In a June 1997 letter to the FDA, Defendants admitted that they were aware that “air blown intraoperatively across the surgical wound may result in airborne contamination.” Defendants were supposed to address this issue in their Bair Hugger. Instead, Defendants simply told the FDA that they had addressed the flaw by employing a tape barrier in all of their Bair Hugger models and that this tape barrier was intended to block air from the surgical site. Defendants knew or should have known that this was a misrepresentation to the FDA, as the statement was entirely erroneous. Not only are many of the Bair Hugger models not equipped with a taped edge at all, but even the use of a taped edge cannot prevent hot air from migrating up from the floor and the warm air that was forced down out of the Bair Hugger returns to the operating field and brings the contaminated bacteria and other pathogens with it. When Defendants made these representations, they knew or should have known they were false.

14. Defendants made additional misrepresentations to the FDA when in 2000 they sent a communication claiming the Bair Hugger’s filtration system met the strict High Efficiency Particulate Air (“HEPA”) standards. To qualify as HEPA compliant by US government

standards, an air filter must remove (from the air that passes through) 99.97% of particles that have a size of 0.3 μm (micrometers) or larger. By contrast, the Bair Hugger filter removes at most only 65% of these particles. Defendants knew that the Bair Hugger has never met these standards, and knew these statements to the FDA were false when they made them in 2000.

15. Rather than fix these known defects, Defendants instead increased the likelihood of infections by further reducing the efficiency of the air filtration in the Bair Hugger sometime between 2002 and 2009.

16. The reduction in efficiency resulted in an increase in contamination with bacteria and other pathogens of the internal airflow paths of the Bair Huggers themselves. Specifically, these pathogens incubate and proliferate in the internal airflow paths of the Bair Hugger devices.

17. These pathogens are then expelled from the Bair Hugger as part of the device's outward air flow process. The pathogens are then released into the operating room, significantly increasing the amount of infectious agents present in the sterile field. The warmer air from the Bair Hugger causes these pathogens to rise up into the operating wound after escaping the surgical drape.

18. Defendants have been aware of the above described contamination of the airflow paths of the Bair Hugger since at least 2009.

19. Adding to Defendants' knowledge has been the medical community, which has published numerous peer-reviewed studies detailing the dangerous defects of 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.

A prudent manufacturer would have taken their knowledge as demonstrated to the FDA in 1997 and 2000, their knowledge of the potential for contamination as of 2009 at the latest as described above, and the publications described in this paragraph and redesigned and improved their product.

20. Instead and despite this knowledge, Defendants continue to provide false and misleading information to the public and the medical community. Rather than fixing these problems, Defendants instead increased their efforts to mislead the public and healthcare community and promote the Bair Hugger.

21. These misleading statements include attempts to focus on the rate at which air moves in the operating room and consequently draw attention away from the real issue with the Bair Hugger warming systems, which is the heat of the air that has been warmed by the Bair Hugger and is forced out onto the floor and circulates pathogens and infectious agents into the surgical site when it rises.

22. For example, in advertisements on Defendants' Bair Hugger website, [www.fawfacts.com/laminar airflow](http://www.fawfacts.com/laminar_airflow), last visited on September 7, 2015, the Defendants make the following inaccurate claims about the Bair Hugger:

- a. That the “[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.”; and,
- 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.”

Defendants knew or should have known that these statements are false. Medical literature and Defendants’ own knowledge as described above make clear that the Bair Hugger has a significant impact on the laminar airflow system in the operating room, and that revisions or modifications to the Bair Hugger were necessary.

23. The claims from the preceding paragraph are not new claims from Defendants. Defendants have been making these intentionally misleading statements to the medical community and public for years. For example, Defendants produced an advertisement that has appeared in multiple medical publications beginning in 2010 that made the following 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.”

Scientific research published both before and after this statement has demonstrated the above claims are false. Not only are they false, they are deliberately misleading. The Bair Hugger has a significant effect on the laminar flow of the operating room due to its convective airflow patterns. This advertisement is still available on Defendants’ website at <http://www.fawfacts.com/asset/zn062p/> (last accessed September 7, 2015).

24. Additional examples of misleading advertising include a statement from Defendants’ public relations and communications specialist Greta Deutsch from the July 2012

issue of *Healthcare Purchasing News*. In that publication, Ms. 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.” These statements continue to ignore the published literature, including at least three studies published at least the year prior to the statements made by Ms. Deutsch as detailed above, and Defendants’ own internal knowledge of the adverse effects the Bair Hugger has on laminar airflow in the operating room and the potential for infections.

25. Despite the representations of Defendants, the Bair Hugger is neither safe nor effective for use in surgeries such as the kind of surgery performed on Plaintiff.

26. The website maintained by Defendants to promote the Bair Hugger, www.fawfacts.com, falsely claims that the Bair Hugger decreases the bacterial count at the surgical site, has no significant effect on operating room airflow, and that the air from the warming blanket is completely isolated from the surgical site.

27. 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 a surgery of the kind performed on Plaintiff if they were fully apprised of the dangers and risks associated with doing so. However, through misrepresentations to the public (including Plaintiff), the medical community (including Plaintiff’s physicians), and the FDA, Defendants actively and knowingly concealed the propensity of the Bair Hugger to cause significant infection in surgeries, including but not limited to the kind of surgery performed on Plaintiff.

PARTIES AND CITIZENSHIP

28. Plaintiff is a resident and citizen of Los Angeles County, CA.

29. Defendants' defective and unreasonably dangerous medical device, the Bair Hugger, was used in conjunction with a surgical procedure performed on Plaintiff.

30. Defendant 3M is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 3M Corporate Headquarters, 3M Center, 2501 Hudson Road, St. Paul, MN 55144-1000. 3M can be served at CT Corporation System, Inc., 100 S 5th Street #1075, Minneapolis, MN 55402.

31. 3M is in the business of designing, manufacturing, marketing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, advertising, and distributing its products, including its patient warming system, the Bair Hugger.

32. 3M does business in the state of Minnesota through maintaining its principal place of business in the state, as well as through the sale of Bair Hugger and other products in the state.

33. Defendant Arizant is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 10393 W 70th St, Eden Prairie, MN 55344. Arizant conducts business throughout the United States, including the state of Minnesota, and is a wholly owned subsidiary of Defendant 3M.

34. At all times relevant, Defendants were engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce throughout the United States, either directly or indirectly through third parties, subsidiaries or related entities, the Bair Hugger.

JURISDICTION AND VENUE

35. This court has jurisdiction over this action pursuant to 28 U.S.C. §1332. Plaintiff is a citizen of a different state from the states where Defendants are incorporated and have their

respective principal places of business. The amount in controversy exceeds \$75,000.00, exclusive of interest and costs.

36. Venue in this District is proper in that Defendants maintain their principal places of business in this District, conduct substantial business in this District, and are therefore subject to personal jurisdiction in this District.

CASE SPECIFIC ALLEGATIONS

37. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further alleges as follows:

38. On March 4, 2014, Plaintiff Manuel Griego underwent a left knee arthroplasty, a surgical procedure wherein Plaintiff's healthcare providers used a Bair Hugger manufactured by Defendants.

39. As a result of the use of the Bair Hugger warming system during Plaintiff's surgery, bacteria and other pathogens were disseminated into Plaintiff's open surgical site, and as a result Plaintiff developed a coagulase-negative staphylococci infection.

40. Defendants, directly or through their agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed and sold the Bair Hugger to Plaintiff's healthcare providers.

41. Due to the infection, Plaintiff suffered substantial injuries, including at least five additional surgical procedures to treat the infection, including removal of the original implant, placement and removal of a PICC line for antibiotic treatment of the infection, placement of a spacer for three months to battle the infection, and the placement of a new knee prosthesis.

42. Plaintiff now suffers and will continue to suffer from permanent damages as a result of the Bair Hugger-induced infection, including but not limited to the five additional

surgical procedures to replace the implant and clean the infected area within one year of the revision implant surgery.

43. Defendants concealed information from Plaintiff, Plaintiff's physicians, and the public at large about the risk of the Bair Hugger causing unreasonable harm. Defendants continue to conceal this information today.

44. After the Bair Hugger was used in Plaintiff's surgery and as a result of its use, Plaintiff suffered serious and life-threatening side effects and injuries, including but not limited to a coagulase-negative staphylococci) infection, five additional surgical procedures to replace the implant and clean the infected area within one year of the revision implant surgery and related sequelae requiring hospitalization, several months in a long term care facility, medical therapy, continuing treatment, and medical monitoring. Further personal injuries suffered by Plaintiff include, but are not limited to, pain and suffering, permanent bodily impairment, mental anguish and diminished enjoyment of life.

45. As a result of the failure of Defendants' Bair Hugger to maintain the sterility of the surgical area and Defendants' 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 Defendants' acts, omissions and misrepresentations.

FIRST CAUSE OF ACTION:
STRICT LIABILITY: DEFECTIVE DESIGN AND MANUFACTURE

46. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further alleges as follows:

47. Defendants are the manufacturers and/or suppliers of Bair Hugger and are strictly liable to Plaintiff for manufacturing, designing, packaging, labeling, marketing, advertising, distributing, selling and placing the Bair Hugger used in Plaintiff's surgery into the stream of commerce.

48. Bair Hugger, manufactured and/or supplied by Defendants, was defective in design in that when it left the hands of the manufacturer and/or suppliers, it was unreasonably dangerous. It was more dangerous than an ordinary consumer would expect in that the Bair Hugger caused convection currents that disrupt the downward airflow of the operating room. These currents caused the Bair Hugger to fail to perform safely when used by ordinary consumers, including Plaintiff and Plaintiff's healthcare providers, including when it was used as intended and in a reasonably foreseeable manner.

49. Additionally, the Bair Hugger's internal airflow passageways become infected and contaminated with bacteria and other pathogens by way of its non-HEPA compliant filter. These infections and contaminations happened when the Bair Hugger was used by consumers and healthcare providers in the way it was ordinarily used, and is therefore unreasonably dangerous, and is more dangerous than an ordinary consumer would expect, and more dangerous than other alternatives.

50. Bair Hugger was defective in design in that, when it left the hands of the manufacturer and when it was used in surgeries the types of which Plaintiff underwent, the foreseeable risks exceeded the benefits associated with the product's design.

51. At all times relevant to this action, an economically and technologically feasible safer alternative design existed in that they provide equal or greater efficacy and far less risk.

52. Defendants marketed, distributed, and/or sold the Bair Hugger used in Plaintiff's surgery without adequately warning the medical community, Plaintiff, or Plaintiff's physicians that the Bair Hugger would circulate air in the operating room which contained infectious agents and that the heated air from the Bair Hugger would be pushed down to the floor and pick up floor air that was contaminated with pathogens and deposit the pathogens into the surgical site, causing deep joint infections, and requiring further treatment, including surgery and/or amputation.

53. Defendants have introduced a product into the stream of commerce which is dangerous and unsafe in that the harm of the Bair Hugger outweighs any benefit derived therefrom. The unreasonably dangerous nature of the Bair Hugger caused serious harm to Plaintiff.

54. Defendants manufactured, marketed, promoted and sold a product that was not merchantable and not reasonably suited to the use intended, and its condition when sold was the proximate cause of the injuries sustained by Plaintiff.

55. The Bair Hugger manufactured, marketed, promoted and sold by Defendants was expected to, and did, reach Plaintiff and Plaintiff's surgeon without substantial change in the condition in which it was sold.

56. Defendants are strictly liable to Plaintiff for designing, manufacturing, and placing into the stream of commerce the Bair Hugger system, which was unreasonably dangerous for its reasonably foreseeable uses because of its design and manufacturing defects. The conduct of Defendants, jointly and severally, caused and/or increased the risk of harm of, and the grievous injuries and damages sustained by Plaintiff.

57. As a direct and proximate result of Defendants' defective design and manufacturing of the Bair Hugger, Plaintiff suffered severe injuries, including a coagulase-negative staphylococci infection requiring at least five additional surgical procedures to clean the infected area and replace the knee implant. Plaintiff has suffered damages and incurred and will continue to incur significant expenses for medical care and treatment, suffered economic loss, and was otherwise physically, emotionally and economically injured. As a result of Plaintiff's infection, Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life and a diminished quality of life. In addition, Plaintiff has suffered mental distress and anguish and has further suffered wage loss and loss of earning capacity.

58. The defective design and manufacture of the Bair Hugger was a cause of Plaintiff's injuries.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and statutory damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

SECOND CAUSE OF ACTION:
STRICT LIABILITY: FAILURE TO WARN

59. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further alleges as follows:

60. Bair Hugger is a defective and therefore unreasonably dangerous product, because its labeling fails to adequately warn consumers and the healthcare community that, among other things, the Bair Hugger would circulate air in the operating room which contained infectious agents and that the heated air from the Bair Hugger would be pushed down to the floor and pick up floor air that was contaminated with pathogens and deposit the pathogens into the surgical

site, causing deep joint infections, and requiring further treatment, including surgery and/or amputation.

61. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the medical device, Bair Hugger, and directly advertised or marketed the product to consumers, including Plaintiff and Plaintiff's physicians, and therefore had a duty to warn of the risks associated with the use of Bair Hugger.

62. Bair Hugger was under the exclusive control of Defendants and was unaccompanied by appropriate warnings regarding all of the risks associated with its use. The warnings given did not accurately reflect the risk, incidence, symptoms, scope or severity of such injuries to the consumer or physicians. The promotional activities of Defendants further diluted or minimized the warnings given with the product.

63. Defendants downplayed the serious and dangerous side effects of the Bair Hugger to encourage sales of the product; consequently, Defendants placed its profits above its customers' safety.

64. The Bair Hugger was defective and unreasonably dangerous when it left the possession of Defendants in that it contained warnings insufficient to alert Plaintiff to the dangerous risks associated with it. Even though Defendants knew or should have known of the risks associated with Bair Hugger, they still failed to provide warnings that accurately reflected the signs, symptoms, incidences, scope, or severity of the risks associated with the product.

65. 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.

66. Plaintiff and Plaintiff's healthcare providers could not have discovered any defect in Bair Hugger through the exercise of reasonable care.

67. Defendants, as a manufacturer of medical and surgical devices, is held to the level of knowledge of an expert in the field and, further, Defendants had knowledge of the dangerous risks and side effects of Bair Hugger.

68. Plaintiff did not have the same knowledge as Defendants and no adequate warning was communicated to Plaintiff's physician(s).

69. Defendants had a continuing duty to warn consumers, including Plaintiff and Plaintiff's physicians, and the medical community of the dangers associated with Bair Hugger, and by negligently and/or wantonly failing to adequately warn of the dangers associated with its use, Defendants breached their duty.

70. Although Defendants knew, or were reckless in not knowing, of the defective nature of Bair Hugger, they continued to manufacture, design, formulate, test, package, label, produce, create, made, construct, assemble, market, advertise, distribute and sell Bair Hugger without providing adequate warnings and instructions concerning the use of Bair Hugger so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious, and deliberate disregard of the foreseeable harm caused by Bair Hugger.

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

72. As a direct and proximate result of Defendants' failure to warn, Plaintiff suffered severe injuries, including a coagulase-negative staphylococci infection requiring at least five

additional surgical procedures to clean the infected area and replace the knee implant. Plaintiff has suffered damages and incurred and will continue to incur significant expenses for medical care and treatment, suffered economic loss, and was otherwise physically, emotionally and economically injured. As a result of Plaintiff's infection, P Hugger being used during Plaintiff's surgery. Plaintiff will also require future medical care, including physical therapy, additional medical monitoring, pain management, and possibly additional surgical intervention. As a result of Plaintiff's infection, Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life and a diminished quality of life. In addition, Plaintiff has suffered mental distress and anguish and has further suffered wage loss and loss of earning capacity.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and statutory damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

THIRD CAUSE OF ACTION:
NEGLIGENCE

73. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further alleges as follows:

74. At all times relevant to this action, Defendants owed Plaintiff a duty to exercise reasonable care when designing, researching, developing, manufacturing, inspecting, marketing, advertising, distributing, and selling the Bair Hugger, which Defendants introduced into the stream of commerce, including a duty to insure that users would not suffer from unreasonable, dangerous, or untoward side effects from its use.

75. At all times relevant to this action, Defendants had a duty to warn all healthcare providers (including Plaintiff's healthcare providers) and consumers (including Plaintiff) of the risks, dangers, and adverse side effects of the Bair Hugger.

76. At all times relevant to this action, Defendants knew or reasonably should have known that the Bair Hugger was unreasonably dangerous and defective when used as directed and as designed, including but not limited to the following particulars:

- a. When this hot air from the Bair Hugger escapes and is pushed down to the floor, the air picks up bacteria and other pathogens from the floor. When the still warmer air begins to rise after leaving the air current caused by the Bair Hugger, bacteria from the floor of the operating room are deposited into the surgical site.
- b. The Bair Hugger has a propensity to collect bacteria and other infectious agents in its internal airflow paths. These pathogens are then expelled from the Bair Hugger into the operating room, significantly increasing the chances of the patient developing an infection.

77. Upon information and belief, Defendants failed to use reasonable care in designing Bair Hugger in that they:

- a. failed to conduct adequate and appropriate testing of the Bair Hugger before releasing the device to market;
- b. failed to properly and thoroughly analyze the data resulting from the premarketing tests of Bair Hugger;
- c. failed to properly, appropriately, and adequately monitor the post-market performance of the Bair Hugger;
- d. disregarding the safety of users and consumers of Bair Hugger, including Plaintiff herein, by failing adequately to warn of said products' potential harm to humans;
- e. failed to exercise due care when advertising and promoting Bair Hugger; and,
- f. failing to fulfill the standard of care required of a reasonable and prudent manufacturer of surgical products, specifically including products such as the Bair Hugger;
- g. negligently continued to manufacture, market, advertise, and distribute Bair Hugger after Defendants knew or should have known of its adverse effects.

78. A reasonable manufacturer would or should have known that the risks created by Bair Hugger are unreasonably greater than that of other similar products and that Bair Hugger

has no clinical benefit over such other products that compensates in whole or in part for the increased risk.

79. Had Defendants made changes to the Bair Hugger as indicated by their own internal research and/or the research of the medical community and informed the medical community and the public at large that the Bair Hugger could cause infections of the kind suffered by Plaintiff if the Bair Hugger was used in the kind of surgery performed on Plaintiff, then Plaintiff would not have developed an infection and suffered the injuries and damages described above.

80. The product defects alleged above were a substantial contributing cause of the injuries and damages suffered by Plaintiff that would not have occurred but for the use of the Bair Hugger.

81. The injuries and damages suffered by Plaintiff were the reasonably foreseeable results of Defendants' negligence.

82. Defendants are directly liable for the negligent conduct of its actual and/or ostensible employees, servants, and agents. The negligent conduct of these employees, servants, and actual and/or ostensible agents, jointly and severally, caused and/or increased the risk of harm of, and the grievous injuries and damages sustained by, Plaintiff.

83. As a direct and proximate result of Defendants' negligence, Plaintiff suffered severe injuries, including a coagulase-negative staphylococci infection requiring at least five additional surgical procedures to clean the infected area and replace the knee implant. Plaintiff has suffered damages and incurred and will continue to incur significant expenses for medical care and treatment, suffered economic loss, and was otherwise physically, emotionally and economically injured. As a result of Plaintiff's infection, P Hugger being used during Plaintiff's

surgery. Plaintiff will also require future medical care, including physical therapy, additional medical monitoring, pain management, and possibly additional surgical intervention. As a result of Plaintiff's infection, Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life and a diminished quality of life. In addition, Plaintiff has suffered mental distress and anguish and has further suffered wage loss and loss of earning capacity.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and statutory damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

FOURTH CAUSE OF ACTION:
BREACH OF IMPLIED WARRANTY

84. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further alleges as follows:

85. Defendants manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold Bair Hugger as safe for use by the public at large, including Plaintiff, whose physicians used Bair Hugger during Plaintiff's surgery.

86. Defendants knew the use for which its product was intended and impliedly warranted the product to be of merchantable quality, safe and fit for use.

87. Plaintiff and Plaintiff's physicians reasonably relied on the skill and judgment of Defendants, and as such its implied warranty, in using Bair Hugger.

88. At all times relevant to this action, Defendants had a duty to warn all healthcare providers (including Plaintiff's healthcare providers) and consumers (including Plaintiff) of the risks, dangers, and adverse side effects of the Bair Hugger.

89. Bair Hugger was not of merchantable quality or safe or fit for its intended use, because it is unreasonably dangerous and unfit for the ordinary purpose for which it was used.

90. At all times relevant to this action, Defendants knew or reasonably should have known that the Bair Hugger was unreasonably dangerous and defective when used as directed and as designed, including but not limited to the following particulars:

- a. When the hot air from the Bair Hugger escapes and is pushed down to the floor, the air picks up bacteria and other pathogens from the floor. When the still warmer air begins to rise after leaving the air current caused by the Bair Hugger, bacteria from the floor of the operating room are deposited into the surgical site.
- b. The Bair Hugger has a propensity to collect bacteria and other infectious agents in its internal airflow paths. These pathogens are then expelled from the Bair Hugger into the operating room, significantly increasing the chances of the patient developing an infection.

91. Defendants were aware that consumers, including Plaintiff, would use the Bair Hugger for treatment in conjunction with surgical procedures of the kind performed on Plaintiff.

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

93. Had Defendants made changes to the Bair Hugger as indicated by their own internal research and/or the research of the medical community and informed the medical community and the public at large that the Bair Hugger could cause infections of the kind suffered by Plaintiff if the Bair Hugger was used in the kind of surgery performed on Plaintiff, then Plaintiff would not have developed an infection and suffered the injuries and damages described above.

94. The product defects alleged above were a substantial contributing cause of the injuries and damages suffered by Plaintiff that would not have occurred but for the use of the Bair Hugger.

95. The injuries and damages suffered by Plaintiff were the reasonably foreseeable results of Defendants' negligence.

96. As a direct and proximate result of Defendants' breach of implied warranty, Plaintiff suffered severe injuries, including a coagulase-negative staphylococci infection requiring at least five additional surgical procedures to clean the infected area and replace the knee implant. Plaintiff has suffered damages and incurred and will continue to incur significant expenses for medical care and treatment, suffered economic loss, and was otherwise physically, emotionally and economically injured. As a result of Plaintiff's infection, P Hugger being used during Plaintiff's surgery. Plaintiff will also require future medical care, including physical therapy, additional medical monitoring, pain management, and possibly additional surgical intervention. As a result of Plaintiff's infection, Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life and a diminished quality of life. In addition, Plaintiff has suffered mental distress and anguish and has further suffered wage loss and loss of earning capacity.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and statutory damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

FIFTH CAUSE OF ACTION:
BREACH OF EXPRESS WARRANTY

97. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further alleges as follows:

98. The aforementioned designing, manufacturing, marketing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, advertising, and

distributing of Bair Hugger were expressly warranted to be safe by Defendants for Plaintiff and members of the public generally.

99. 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, and that it was adequately tested.

100. At the time of the making of these express warranties, Defendants had knowledge of the foreseeable purposes for which Bair Hugger was to be used and Defendants warranted Bair Hugger to be in all respects safe, effective and proper for such purposes.

101. Bair Hugger does not conform to these express warranties and representations because Bair Hugger is not safe or effective and produced serious side effects.

102. 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.

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

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

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

106. As a direct and proximate result of Defendants' breach of implied warranty, Plaintiff suffered severe injuries, including a coagulase-negative staphylococci infection requiring at least five additional surgical procedures to clean the infected area and replace the knee implant. Plaintiff has suffered damages and incurred and will continue to incur significant expenses for medical care and treatment, suffered economic loss, and was otherwise physically,

emotionally and economically injured. As a result of Plaintiff's infection, P Hugger being used during Plaintiff's surgery. Plaintiff will also require future medical care, including physical therapy, additional medical monitoring, pain management, and possibly additional surgical intervention. As a result of Plaintiff's infection, Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life and a diminished quality of life. In addition, Plaintiff has suffered mental distress and anguish and has further suffered wage loss and loss of earning capacity.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and statutory damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

SIXTH CAUSE OF ACTION:
NEGLIGENT MISREPRESENTATION

107. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further alleges as follows:

108. Defendants, in the course of their business, negligently misrepresented and failed to disclose material facts concerning the risks of use of the Bair Hugger in surgeries, particularly in surgeries of the kind which was performed on Plaintiff.

109. Defendants have known of the increased risks of infection from use of Bair Hugger since at least 1997, and of the increased risk of infections caused by the modifications made to the Bair Huggers design since at least 2009 as detailed above.

110. Defendants continue marketing their Bair Hugger for use in all surgical procedures, contrary to evidence presented in the medical literature and contrary to their own internal knowledge. These misleading marketing efforts have been ongoing since at least 1997.

111. Defendants, having undertaken the designing, manufacturing, marketing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, advertising, and distributing of Bair Hugger, owed a duty to provide accurate and complete information regarding Bair Hugger.

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

- a. 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. Defendants represented the Bair Hugger was safer than other patient warming systems.

113. These misrepresentations were made by Defendants with the intent to induce Plaintiff and Plaintiff's healthcare providers to use Bair Hugger, which caused Plaintiff's injury.

114. At the time of Defendants' misrepresentations and omissions, Plaintiff was ignorant of the falsity of these statements and reasonably believed them to be true.

115. Defendants breached its duties to Plaintiff by providing false, incomplete and/or misleading information regarding their product.

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

117. As such, Defendants failed to exercise reasonable care of competence in obtaining or communicating truthful and accurate information to Plaintiff and Plaintiff's physicians, and failed to comply with the existing standard of care.

118. Defendants are directly liable for the negligent conduct of its actual and/or ostensible employees, servants, and agents. The negligent conduct of these employees, servants,

and actual and/or ostensible agents, jointly and severally, caused and/or increased the risk of harm of, and the grievous injuries and damages sustained by, Plaintiff.

119. As a direct and proximate result of Defendants' negligent misrepresentations, Plaintiff suffered severe injuries, including a coagulase-negative staphylococci infection requiring at least five additional surgical procedures to clean the infected area and replace the knee implant. Plaintiff has suffered damages and incurred and will continue to incur significant expenses for medical care and treatment, suffered economic loss, and was otherwise physically, emotionally and economically injured. As a result of Plaintiff's infection, P Hugger being used during Plaintiff's surgery. Plaintiff will also require future medical care, including physical therapy, additional medical monitoring, pain management, and possibly additional surgical intervention. As a result of Plaintiff's infection, Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life and a diminished quality of life. In addition, Plaintiff has suffered mental distress and anguish and has further suffered wage loss and loss of earning capacity.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and statutory damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

SEVENTH CAUSE OF ACTION:
FRAUDULENT MISREPRESENTATION

120. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further alleges as follows:

121. Defendants, through their employees and agents, knowingly and intentionally made material misrepresentations to Plaintiff, Plaintiff's physicians, and to the public that the

Bair Hugger warming system was safe for use in surgeries, including the surgery performed on Plaintiff.

122. Defendants knew as early as 1997 and at least by 2009 that the Bair Hugger had an increased risk of causing infection during surgery.

123. Defendants were aware at least by 2009 that modifications they had made to the design of the Bair Hugger were contributing to the incubation and circulation of bacteria and other pathogens in and around the operating room, including at the patient's open surgical site as detailed above.

124. Despite this knowledge, Defendants continue to provide false information to Plaintiff, Plaintiff's physicians, the medical community, the FDA, and the public at large about the safety and efficacy of the Bair Hugger as detailed above.

125. Defendants, having undertaken the designing, manufacturing, marketing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, advertising, and distributing of Bair Hugger described herein, owed a duty to provide accurate and complete information regarding Bair Hugger.

126. Defendants fraudulently misrepresented material facts and information regarding Bair Hugger including, but not limited to, its propensity to cause serious physical harm.

127. At the time of Defendants' fraudulent misrepresentations and omissions, Plaintiff and Plaintiff's healthcare providers were unaware and ignorant of the falsity of the statements and reasonably believed them to be true.

128. Defendants knew this information to be false, incomplete and misleading.

129. Defendants intended to deceive and mislead Plaintiff so that Plaintiff might rely on these fraudulent misrepresentations.

130. Plaintiff and Plaintiff's physicians had a right to rely on and did reasonably rely upon Defendants' deceptive, inaccurate and fraudulent misrepresentations. In the absence of Defendants' representations, the Bair Hugger would not be used in surgeries such as the one at issue in this case.

131. As a direct and proximate result of Defendants' fraudulent misrepresentation, Plaintiff suffered severe injuries, including a coagulase-negative staphylococci infection requiring at least five additional surgical procedures to clean the infected area and replace the knee implant. Plaintiff has suffered damages and incurred and will continue to incur significant expenses for medical care and treatment, suffered economic loss, and was otherwise physically, emotionally and economically injured. As a result of Plaintiff's infection, P Hugger being used during Plaintiff's surgery. Plaintiff will also require future medical care, including physical therapy, additional medical monitoring, pain management, and possibly additional surgical intervention. As a result of Plaintiff's infection, Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life and a diminished quality of life. In addition, Plaintiff has suffered mental distress and anguish and has further suffered wage loss and loss of earning capacity.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and statutory damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

EIGHTH CAUSE OF ACTION:
FRAUD BY CONCEALMENT

132. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further alleges as follows:

133. Any applicable statutes of limitations have been tolled by the knowing and active concealment and denial of material facts known by Defendants when it had a duty to disclose those facts. Defendants kept Plaintiff and Plaintiff's healthcare providers ignorant of vital information essential to the pursuit of these claims, without any fault or lack of diligence on Plaintiff's part, for the purposes of continuing to increase their profits through sales of their Bair Hugger and also for purposes of obtaining delay on Plaintiff's part in filing a complaint on these causes of action. Defendants had a duty and obligation to disclose to Plaintiff that Bair Hugger was dangerous and likely to cause serious health consequences to users when used as prescribed.

134. Defendants intentionally, willfully, and maliciously concealed and/or suppressed the facts set forth above from Plaintiff with the intent to defraud as herein alleged.

135. Defendants knew as early as 1997 and at least by 2009 that the Bair Hugger had an increased risk of causing infections through the ordinary use of the product. Defendants concealed this information from Plaintiff and Plaintiff's healthcare providers, and the public at large, and to date still have not provided an adequate warning for this product.

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

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

138. As a proximate result of the concealment and/or suppression of the facts set forth above, Plaintiff has proximately sustained damage, as set forth herein.

139. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, Plaintiff suffered profound injuries, required medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and statutory damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

NINTH CAUSE OF ACTION:
VIOLATION OF MINNESOTA'S CONSUMER PROTECTION AND
DECEPTIVE TRADE PRACTICES LAWS

140. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs.

141. Defendants have violated and continue to violate Minnesota Consumer Protection statutes, Minn. Stat. §§ 325F.67 and 325F.69, and Minnesota's Deceptive Trade Practices statute, Minn. Stat. § 325D.44.

142. At all times relevant, Minn. Stat. §§ 325F.68-70, *et seq.*, made "the act, use, or employment of any person of any fraud, false pretense, false promise, misrepresentation, misleading statement or deceptive practice, with the intent that others rely thereon in connection with the sale of any merchandise, whether or not any person has in fact been misled, deceived, or damaged thereby, is enjoyable" unlawful.

143. Defendants violated the Minnesota Consumer Fraud Act by the use of false and misleading misrepresentations or omissions of material fact in connection with the marketing, promotion, and sale of the Bair Hugger. Defendants communicated the purported benefits of the Bair Hugger while failing to disclose the serious and dangerous side effects related to the use of the Bair Hugger with the intent that consumers, like Plaintiff, and their healthcare providers rely

upon the omissions and misrepresentations and recommend and use the Bair Hugger, respectively.

144. Defendants 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, 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; and,
- d. Falsely stating, knowingly or with reason to know, that services or repairs are not needed.

145. As a result of violating the Minnesota Consumer Fraud Act, Defendants caused Plaintiff to use the Bair Hugger during surgery as described above, causing severe injuries and damages as previously described herein.

146. As a result of violating the Minnesota Consumer Protection statutes and Minnesota's Deceptive Trade Practices statute, Defendants caused Plaintiff to use Bair Hugger during Plaintiff's surgery, causing severe injuries and damages as previously described herein.

147. As a result of Defendants' violations of the Minnesota Consumer Protection statutes and Minnesota's Deceptive Trade Practices statute, Plaintiff seeks damages and costs as provided by the Act.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and statutory damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

RELIEF REQUESTED

WHEREFORE Plaintiff prays for judgment against Defendants and, as appropriate to each cause of action alleged and as appropriate to the standing of the Plaintiff, as follows:

1. Past and future general damages, the exact amount of which has yet to be ascertained, in an amount according to proof at the time of trial;
2. Past and future economic and special damages according to proof at trial;
3. Loss of earnings and impaired earning capacity according to proof at trial;
4. Medical expenses, past and future, according to proof at the time of trial;
5. Past and future pain and suffering damages, including mental and emotional stress arising from Plaintiff's physical injuries, according to proof at the time of trial;
6. Equitable relief as requested and/or as the Court deems just and proper;
7. Declaratory judgment that Defendants are liable to Plaintiff for all future evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses, costs and losses caused by Defendants' wrongdoing;
8. Medical monitoring, whether denominated as damages or in the form of equitable relief according to proof at the time of trial;
9. Costs of suit incurred herein;
10. Pre-judgment interest as provided by law; and
11. Such other and further relief as the Court may deem just and proper.

Plaintiff seeks a trial by jury on all issues.

Respectfully Submitted,

JOHNSON BECKER, PLLC

Date: October 9, 2015

By: s/ Michael K. Johnson
Michael K. Johnson (MN #258696)
Timothy J. Becker (MN #256663)

Rolf T. Fiebiger (MN #391138)
JOHNSON BECKER, PLLC
33 South Sixth Street, Suite 4530
Minneapolis, Minnesota 55402
Ph: (612) 436-1800
Fax: (612) 436-1801
mjohnson@johnsonbecker.com
tbecker@johnsonbecker.com
rfiebiger@johnsonbecker.com

Attorneys for Plaintiff

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
Manuel G. Griego
(b) County of Residence of First Listed Plaintiff Los Angeles County, CA
(c) Attorneys (Firm Name, Address, and Telephone Number)
Michael K. Johnson, Timothy J. Becker, Rolf T. Fiebiger, Johnson Becker, PLLC
33 South Sixth Street, Suite 4530, Minneapolis, MN 55402; (612) 436-1812

DEFENDANTS
3M Company and Arizant Healthcare, Inc.
County of Residence of First Listed Defendant Ramsey County, MN
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
2 U.S. Government Defendant
3 Federal Question (U.S. Government Not a Party)
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)
Citizen of This State
Citizen of Another State
Citizen or Subject of a Foreign Country
PTF DEF
1 1 Incorporated or Principal Place of Business In This State
2 2 Incorporated and Principal Place of Business In Another State
3 3 Foreign Nation
4 4
5 5
6 6

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

Table with 5 columns: CONTRACT, REAL PROPERTY, TORTS, CIVIL RIGHTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES. Contains various checkboxes for legal categories like Insurance, Land Condemnation, Personal Injury, Habeas Corpus, etc.

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:
Product liability action based on Defendants' defective surgical product Bair Hugger

VII. REQUESTED IN COMPLAINT:
CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.
DEMAND \$ 75,000
CHECK YES only if demanded in complaint:
JURY DEMAND: Yes No

VIII. RELATED CASE(S) IF ANY
(See instructions):
JUDGE
DOCKET NUMBER

DATE 10/09/2015
SIGNATURE OF ATTORNEY OF RECORD s/ Michael K. Johnson

FOR OFFICE USE ONLY
RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE