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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF CALIFORNIA

ROBERT NELSON, an individual,
Plaintiff,

v.

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

CASE NO. _____

COMPLAINT AND DEMAND FOR JURY TRIAL

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

This is an action for damages relating to Defendants' 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 of Sacramento, California.

1 2. Defendant 3M is a corporation organized and existing under the laws of the State
2 of Delaware, with its principal place of business located in Maplewood, Minnesota. 3M is
3 engaged in the business of researching, developing, designing, licensing, manufacturing,
4 distributing, supplying, selling, marketing and introducing into interstate commerce, either
5 directly or indirectly through third parties or related entities, its products, including the Bair
6 Hugger.

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

10 **II. JURISDICTION AND VENUE**

11 4. This Court has jurisdiction pursuant to 28 U.S.C. § 1332, as complete diversity
12 exists between Plaintiff and Defendants, and the amount in controversy exceeds \$75,000.
13 Defendants are subject to *in personam* jurisdiction in this court, and venue is proper within this
14 district pursuant to 28 U.S.C. § 1391, as a substantial number of the events, actions, or omissions
15 giving rise to the Plaintiff's claims occurred in this district. At all times relevant to this matter,
16 Defendants 3M Company ("3M") and Arizant Healthcare Inc. ("Arizant") (collectively the
17 "Defendants") conducted substantial business in this district. Defendants did (and do) business
18 within the state of California and have had substantial, continuous, and systematic contacts with
19 the state of California, and many other states, against thousands of Plaintiffs, including Plaintiff
20 herein, as more fully set forth below. On information and belief, Defendants also marketed,
21 advertised, and sold the defective devices in the state of California, and many other states, made
22 material omissions and representations in each of these districts, and breached warranties in these
23 districts.

24 **III. SUMMARY OF THE CASE**

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

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

7. On April 14, 2014, the Bair Hugger was used on Plaintiff during the course of Plaintiff's right 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 was ordered to take IV and oral antibiotics with an additional surgical procedure to irrigate and debride the infected area, and Plaintiff continues to suffer substantial damages, including but not limited to taking costly oral antibiotics for a substantial amount of time and impaired mobility, making the simple movement of walking a challenge.

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

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

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

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

IV. FACTUAL BACKGROUND

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

1 from the floor of the surgical room into the surgical site.

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

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

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

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

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

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

15 23. In a communication to the Food and Drug Administration ("FDA") in September
16 2000, Defendants represented that the Bair Hugger's filtration system meets HEPA ("High
17 Efficiency Particulate Air") Standards. This statement was false at the time Defendants made it
18 and it remains false today. To meet HEPA standards, an air filter must be capable of removing
19 99.97% of all particles 0.3 microns or larger. The filter of the Bair Hugger, which is marketed as
20 HEPA compliant, is only capable of removing less than 65% of all such particles. When the
21 Defendants made these representations, they had actual knowledge of their falsity.

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

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

7 25. In their website, www.fawfacts.com/laminar_airflow/ (last visited July 17, 2015),
8 the Defendants make the following misrepresentations:

- 9 a. Contamination mobilized by the convection currents generated by the Bair Hugger
10 cannot reach the surgical site because “[a]ir velocity within the operating room is
11 many times stronger than that of a forced-air warming blanket”;
- 12 b. “The air emerging from the blanket is directed downward by the surgical drape
13 and emerges under the operating room table and is drawn away through the
14 laminar system’s return air inlets;”
- 15 c. “It’s been suggested that warm air rising above the Bair Hugger blanket could
16 interfere with the downward laminar flow toward the surgical site. It should be
17 noted that the Bair Hugger warming unit delivers less than one percent of the
18 airflow of a laminar flow system and the momentum of the downward air is far
19 greater than the upward momentum imparted to the air above the blanket.”

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

28 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 Defendants made the following false and deliberately misleading claims:

1 “While simple logic makes it clear that forced air warming has no impact
2 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.”

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

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

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

- 17 a. Albrecht M, et al. Forced-air warming blowers: An evaluation of filtration
18 adequacy and airborne contamination emissions in the operating room. *Am J Infect*
Control 2010;39:321-8;
- 19 b. Leaper D, et al. Forced-air warming: a source of airborne contamination in the
20 operating room? *Orthopedic Rev.* 2009;1(2):e28;
- 21 c. McGovern, P.D., et al. Forced-air warming and ultra-clean ventilation do not mix.
22 *J Bone and Joint Surg-Br.* 2011;93-B(11):1537-1544;
- 23 d. Legg, A. et al. Do forced air patient-warming devices disrupt unidirectional
24 downward airflow? *J Bone and Joint Surg-Br.* 2012;94-B:254-6;
- 25 e. Belani, K., et al. Patient warming excess heat: The effects on orthopedic operating
26 room ventilation performance. *Anesthesia & Analgesia* 2012 (prepublication
27 on-line) 2013;117(2):406-411;
- 28 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.

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

4 31. Rather than alter the design of their product or warn physicians of the dangers
5 associated with the Bair Hugger, as numerous studies confirm, the Defendants have chosen to
6 “double down” on their efforts to promote their defective product.

7 32. Plaintiffs’ physicians relied upon the above representations and advertisements to
8 Plaintiff’s detriment. Any reasonable and competent physician would not use a Bair Hugger in an
9 orthopedic implant surgery if they were fully apprised of the dangers and risks associated with
10 doing so. However, through misrepresentations to the public, the medical community, and the
11 FDA, the Defendants actively and knowingly concealed the propensity of these devices to cause
12 infection in orthopedic implant surgeries.

13 33. As a result of the failure of the Defendants’ Bair Hugger to maintain the sterility
14 of the surgical area and the Defendants’ wrongful conduct in designing, manufacturing, and
15 marketing this defective product, Plaintiff and Plaintiff’s physician were unaware, and could not
16 have reasonably known or have learned through reasonable diligence, that Plaintiff had been
17 exposed to the risks identified in this complaint, and that those risks were the direct and
18 proximate result of the Defendants’ acts, omissions and misrepresentations.

19 **V. CAUSES OF ACTION**

20 **COUNT ONE – Negligence**

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

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

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

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

- b. Failing to properly and thoroughly analyze the data resulting from the pre-market tests of the Bair Hugger;
- c. Failing to conduct sufficient post-market testing and surveillance of the Bair Hugger;
- d. Designing, manufacturing, marketing, advertising, distributing, and selling the Bair Hugger to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of the Bair Hugger and without proper instructions to avoid the harm which could foreseeably occur as a result of using the device;
- e. Failing to exercise due care when advertising and promoting the Bair Hugger; and
- f. Negligently continuing to manufacture, market, advertise, and distribute the Bair Hugger after Defendants knew or should have known of its adverse effects.

37. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff suffered Spares Enterococcus Faecalis infection, requiring an additional surgical procedure to irrigate and debride the infected area, and Plaintiff was subsequently hospitalized for an aggressive treatment of the infection. Consequently, Plaintiff has suffered damages and incurred and will continue to incur medical expenses as a result of using the Bair Hugger. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting condition and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage earning capacity.

38. The Defendants' conduct as described above was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff. Defendants' conduct warrants, if allowed by the Court upon motion, an award of punitive damages against Defendants in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

COUNT TWO – STRICT LIABILITY

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

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

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

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

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

44. 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.

45. 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

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

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

1 duty to warn of the risks associated with the use of the Bair Hugger.

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

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

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

14 51. As a direct and proximate result of the Defendants' actions, omissions and
15 misrepresentations, Plaintiff suffered an infection, requiring an additional surgical procedure to
16 clean the infected area and/or remove the hip implant, and was subsequently hospitalized for an
17 aggressive treatment of the infection. Consequently, Plaintiff has suffered damages and incurred
18 and will continue to incur medical expenses as a result of using the Bair Hugger. Plaintiff has also
19 suffered and will continue to suffer diminished capacity of the enjoyment of life, a diminished
20 quality of life, increased risk of premature death, aggravation of preexisting conditions and
21 activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and
22 costs include care for hospitalizations, physician care, monitoring, treatment, medications and
23 supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering
24 and loss of wages and wage earning capacity.

25 52. The Defendants' conduct described above was committed with knowing,
26 conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and
27 safety of consumers such as Plaintiff. Defendants' conduct warrants, if allowed by the Court
28 upon motion, an award of punitive damages against Defendants in an amount appropriate to

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

2 **B. Strict Liability - Defective Design and Manufacture**

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

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

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

- 9 a. would have prevented or significantly reduced the risk of Plaintiff's infection and
10 subsequent injuries (including additional surgical procedures to clean the infected
11 area and/or remove the implant);and
12 b. would not have impaired the utility of the device

13 56. Specifically, the Bair Hugger is defective in its design in that it is not reasonably
14 fit, suitable or safe for its intended purpose or its foreseeable risks exceed the benefits associated
15 with its design.

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

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

27 59. As a direct and proximate result of the Defendants' actions, omissions and
28 misrepresentations, Plaintiff suffered an infection, requiring an additional surgical procedure to

1 clean the infected area and/or remove the hip implant, and Plaintiff was subsequently hospitalized
2 for an aggressive treatment of the infection. Consequently, Plaintiff has suffered damages and
3 incurred and will continue to incur medical expenses as a result of using the Bair Hugger.
4 Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of
5 life, a diminished quality of life, increased risk of premature death, aggravation of preexisting
6 conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct
7 medical losses and costs include care for hospitalization, physician care, monitoring, treatment,
8 medications and supplies. Plaintiff has incurred and will continue to incur mental and physical
9 pain and suffering and loss wages and wage earning capacity.

10 60. The Defendants' conduct as described above was committed with knowing,
11 conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and
12 safety of consumers such as Plaintiff. Defendants' conduct warrants, if allowed by the Court
13 upon motion, an award of punitive damages against Defendants in an amount appropriate to
14 punish the Defendants and deter them from similar conduct in the future.

15 **COUNT THREE – BREACH OF EXPRESS WARRANTY**

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

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

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

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

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

28 66. At all relevant times, the Bair Hugger was used on Plaintiff by Plaintiff's

1 physicians for the purpose and in the manner intended by Defendants.

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

4 68. As a direct and proximate result of the Defendants' actions, omissions and
5 misrepresentations, Plaintiff suffered an infection, requiring additional surgical procedures to
6 clean the infected area and/or remove the hip implant, and Plaintiff was subsequently hospitalized
7 for an aggressive treatment of the infection. Consequently, Plaintiff has suffered damages and
8 incurred and will continue to incur medical expenses as a result of using the Bair Hugger.
9 Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of
10 life, a diminished quality of life, increased risk of premature death, aggravation of preexisting
11 conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct
12 medical losses and costs include care for hospitalization, physician care, monitoring, treatment,
13 medications and supplies. Plaintiff has incurred and will continue to incur mental and physical
14 pain and suffering and loss wages and wage earning capacity.

15 69. The Defendants' conduct as described above was committed with knowing,
16 conscious, wanton, willful and deliberate disregard for the value of human life and the rights and
17 safety of consumers such as Plaintiff. Defendants' conduct warrants, if allowed by the Court
18 upon motion, an award of punitive damages against Defendants in an amount appropriate to
19 punish the Defendants and deter them from similar conduct in the future.

20 **COUNT FOUR – BREACH OF IMPLIED WARRANTY**

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

22 71. The Defendants designed, manufactured, distributed, advertised, promoted and
23 sold the Bair Hugger.

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

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

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

4 75. The Defendants breached their implied warranty to consumers, including Plaintiff;
5 the Bair Hugger was not of merchantable quality or safe and fit for its intended use.

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

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

10 78. As a direct and proximate result of the Defendants' actions, omissions and
11 misrepresentations, Plaintiff suffered an infection, requiring an additional surgical procedure to
12 clean the infected area and/or remove the hip implant, and Plaintiff was subsequently hospitalized
13 for an aggressive treatment of the infection. Consequently, Plaintiff suffered damages and
14 incurred and will continue to incur medical expenses as a result of using the Bair Hugger.
15 Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of
16 life, a diminished quality of life, increased risk of premature death, aggravation of preexisting
17 conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct
18 medical losses and costs include care for hospitalization, physician care, monitoring, treatment,
19 medications and supplies. Plaintiff has incurred and will continue to incur mental and physical
20 pain and suffering and loss of wages and wage earning capacity.

21 79. The Defendant's conduct as described above was committed with knowing,
22 conscious, wanton, willful and deliberate disregard for the value of human life and the rights and
23 safety of consumers such as Plaintiff. Defendants' conduct warrants, if allowed by the Court
24 upon motion, an award of punitive damages against Defendants in an amount appropriate to
25 punish the Defendants and deter them from similar conduct in the future.

26 **COUNT FIVE – NEGLIGENT MISREPRESENTATION**

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

28 81. The Defendants made negligent misrepresentations with respect to the Bair

1 Hugger including, but not limited to, the following particulars:

- 2 a. The Defendants represented through the labeling,
3 advertising, marketing materials, seminar presentations,
4 publications, notice letters, and regulatory submissions that
5 Bair Hugger has been tested and found to be safe and
6 effective for the warming of patients during orthopedic
7 implant surgery; and
- 8 b. The Defendants represented the Bair Hugger was safer than
9 other patient warming systems.

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

13 83. Plaintiff and Plaintiff's physicians did, in fact, reasonably rely upon the
14 representations.

15 84. As a direct and proximate result of the Defendants' actions, omissions and
16 misrepresentations, Plaintiff suffered an infection, requiring additional surgical procedures to
17 clean the infected area and/or remove the hip implant, and Plaintiff subsequently was hospitalized
18 for an aggressive treatment of the infection. Consequently, Plaintiff has suffered damages and
19 incurred and will continue to incur medical expenses as a result of using the Bair Hugger.
20 Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of
21 life, a diminished quality of life, increased risk of premature death, aggravation of preexisting
22 conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct
23 medical losses and costs include care for hospitalization, physician care, monitoring, treatment,
24 medications and supplies. Plaintiff has incurred and will continue to incur mental and physical
25 pain and suffering and loss of wages and wage earning capacity.

26 85. The Defendants' conduct as described above was committed with knowing,
27 conscious, wanton, willful and deliberate disregard for the value of human life and the rights and
28 safety of consumers such as Plaintiff. Defendants' conduct warrants, if allowed by the Court
upon motion, an award of punitive damages against Defendants in an amount appropriate to
punish the Defendants and deter them from similar conduct in the future.

COUNT SIX – FRAUDULENT MISREPRESENTATION

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

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

- a. The Defendants represented through the labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that 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 Defendants represented Bair Hugger was safer than other patient warming systems.

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

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

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

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

92. The Defendants' fraudulent representations evidence their callous, reckless, and willful indifference to the health, safety, and welfare of consumers, including Plaintiff.

93. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff suffered an infection, requiring an additional surgical procedure to clean the infected area and/or remove the hip implant, and Plaintiff was subsequently hospitalized for an aggressive treatment of the infection. Consequently, Plaintiff has suffered damaged and incurred and will continue to incur medical expenses as a result of using the Bair Hugger. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of

1 life, a diminished quality of life, increased risk of premature death, aggravation of preexisting
2 conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct
3 medical losses and costs include care for hospitalization, physician care, monitoring, treatment,
4 medications and supplies. Plaintiff has incurred and will continue to incur mental and physical
5 pain and suffering and loss of wages and wage earning capacity.

6 94. The Defendants' conduct as described above was committed with knowing,
7 conscious, wanton, willful and deliberate disregard for the value of human life and the rights and
8 safety of consumers such as Plaintiff. Defendants' conduct warrants, if allowed by the Court
9 upon motion, an award of punitive damages against Defendants in an amount appropriate to
10 punish the Defendants and deter them from similar conduct in the future.

11 **COUNTH SEVEN – Fraudulent Concealment**

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

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

- 15 a. The Defendants represented through the labeling,
16 advertising, marketing materials, seminar presentations,
17 publications, notice letters, and regulatory submissions that
18 the Bair Hugger was safe and fraudulently withheld and
19 concealed information about the substantial risk of using
20 Bair Hugger; and
- 21 b. The Defendants represented that Bair Hugger was safe and
22 safer than other alternative systems and fraudulently
23 concealed information that demonstrated that Bair Hugger
24 was not safer than alternatives available on the market.

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

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

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

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

101. As a direct and proximate result of the Defendants' actions, omissions and misrepresentations, Plaintiff suffered an infection, requiring an additional surgical procedure to clean the infected area and/or remove the hip implant, and Plaintiff was subsequently hospitalized for an aggressive treatment of the infection. Consequently, Plaintiff has suffered damaged and incurred and will continue to incur medical expenses as a result of using the Bair Hugger. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage earning capacity.

102. The Defendants' conduct as described above was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff. Defendants' conduct warrants, if allowed by the Court upon motion, an award of punitive damages against Defendants in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against the Defendants, jointly and/or severally, 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 Defendants or to deter the Defendants 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.

Date: September 11, 2015.

KERSHAW, COOK & TALLEY, PC

By: /s/ Stuart C. Talley

Stuart C. Talley (180374)
William A. Kershaw (057486)
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Sacramento, California 95864
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Attorneys For Plaintiff

CIVIL COVER SHEET

Case 2:15-at-00957 Document 1-1 Filed 09/11/15 Page 1 of 1

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

Robert Nelson

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

(c) Attorneys (Firm Name, Address, and Telephone Number)

KERSHAW, COOK & TALLEY PC
William A. Kershaw and Stuart C. Talley
401 Watt Avenue, Sacramento, CA 95864
916-779-7000

DEFENDANTS

3M Company, a Delaware corporation; and Arizant Healthcare, Inc., a Delaware corporation

County of Residence of First Listed Defendant
(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
- ☐ 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)

- | | PTF | DEF | | PTF | DEF |
|---|---------------------------------------|----------------------------|---|----------------------------|---------------------------------------|
| Citizen of This State | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 |
| Citizen of Another State | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input checked="" type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

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

| CONTRACT | TORTS | FORFEITURE/PENALTY | BANKRUPTCY | OTHER STATUTES | |
|---|--|---|---|---|--|
| <input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise | PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice | PERSONAL INJURY <input type="checkbox"/> 365 Personal Injury - Product Liability <input checked="" type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability | <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act IMMIGRATION <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions | <input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609 | <input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes |
| REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property | CIVIL RIGHTS <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education | PRISONER PETITIONS Habeas Corpus: <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty Other: <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement | | | |

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. Section 1332

Brief description of cause:

Products Liability Case Involving the Bair Hugger Forced Air Warming Device

VII. REQUESTED IN COMPLAINT:

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

DEMAND \$

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE

DOCKET NUMBER

DATE

09/11/2015

SIGNATURE OF ATTORNEY OF RECORD

/s/ Stuart C. Talley

FOR OFFICE USE ONLY

RECEIPT #

AMOUNT

APPLYING IFP

JUDGE

MAG. JUDGE