IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF TENNESSEE

JENNIFER WILSON, Plaintiff,	Case No.: COMPLAINT FOR DAMAGES COMPLAINT FOR DAMAGES
NURSE ASSIST, LLC, a limited liability company, d/b/a MCKESSON and STERICARE SOLUTIONS, Defendants.	(1) NEGLIGENCE (2) DESIGN DEFECT (3) FAILURE TO WARN (4) BREACH OF IMPLIED WARRANTY (5) BREACH OF EXPRESS WARRANTY (6) FRAUDULENT CONCEALMENT (7) TENNESSEE CONSUMER PROTECTION ACT OF 1977 (8) PUNITIVE DAMAGES DEMAND FOR JURY TRIAL

COMPLAINT

COMES NOW Plaintiff, JENNIFER WILSON, (hereinafter "Plaintiff"), by and through undersigned counsel, and brings this Complaint against NURSE ASSIST, LLC, a limited liability company d/b/a MCKESSON and STERICARE SOLUTIONS, (collectively, the "Defendants"), and alleges as follows:

1. This is an action for damages arising out of failures relating to Defendants' design, development, testing, assembling, manufacturing, packaging, promoting, marketing, distribution, supplying, and/or selling the defective McKesson saline solution (hereinafter "Saline Solution," "Product," or "Subject Product").

PARTIES

2. Plaintiff, JENNIFER WILSON, is an adult resident and citizen of Lawrence County, Tennessee.

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- 3. Defendant Nurse Assist, LLC ("Nurse Assist"), upon information and belief, is a foreign limited liability company authorized to do business in the state of Tennessee. Nurse Assist was acquired by BPGC Management LP, Spinnaker International LLC and R Investments. At all times relevant to the claims made in this action, Nurse Assist was d/b/a McKesson and/or Stericare Solutions with its principle place of business at 4409 Haltom Road, Haltom City, TX 76117.
- 4. Defendants are independent specialty manufacturers of medical grade saline and water products with a focus on prefilled flush syringes, USP sterile water and saline, sterile saline wound flush and irrigation kits. At all relevant times, Defendants manufactured, marketed, distributed a Saline Solution product which caused the injuries suffered by Plaintiff.

JURISDICTION AND VENUE

- 5. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. \$1332(a) because the parties are citizens of different states and the amount in controversy exceeds \$75,000.00, exclusive of interest and cost.
- 6. Venue is proper in this Court pursuant to 28 U.S.C. §1391 by virtue of the facts that (a) a substantial part of the events or omissions giving rise to the claims occurred in this District, and (b) Defendants' products are produced, sold to, and consumed by individuals in the State of Tennessee, thereby subjecting Defendants to personal jurisdiction in this action and making them all "residents" of this judicial District.
- 7. Defendants have and continue to conduct substantial business in the State of Tennessee and in this District, distribute saline solution products in this District, receive substantial compensation and profits from sales of saline solution products in this District, and made material omissions and misrepresentations and breaches of warranties product safety in this District, so as

to subject them to in personam jurisdiction in this District.

8. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this Court has *in personam* jurisdiction over Defendants because Defendants are present in the State of Tennessee, such that requiring an appearance does not offend traditional notices of fair and substantial justice.

FACTUAL BACKGROUND

- 9. Defendants' products are sterile saline and water solutions used for medical irrigation. These products may be used for: cleaning wounds, flushing out medical tubing, such as catheters, and rinsing body cavities.
- 10. However, in late 2023, it was discovered that the sterile solutions may be contaminated with harmful bacteria, which could cause severe or life-threatening infections.
- 11. In November 2023, a FDA recall was issued for Defendants' Saline Solutions, after it was discovered that development, sterilization, and packaging seal defects could compromise the sterility of the products and allow bacteria to enter and grow within them. This created a serious infection risk for patients throughout the U.S., particularly if they have compromised immune systems, are elderly, have open wounds being treated, or have chronic conditions.
- 12. In April 2024, FDA expanded its recall of saline solutions and related products. This again called into question the underlying development and packaging process employed by Defendants along with the breadth of their products which were contaminated.
- 13. One of the bacterial contaminations which could occur with Defendants' products involved *Vibrio Vulnificus*.

- 14. *Vibrio Vulnificus* is a bacterium that occurs naturally in sea waters and can occur in high numbers in filter-feeding shellfish (oysters, clams, and mussels). The organism is able to cause infection in people through ingestion or open wound exposure and it most often leads to limb amputation or even death if not immediately diagnosed and treated.
- 15. Plaintiff suffers from lymphedema wounds on her legs and receives home health treatment for this condition at her residence in Lawrenceburg, Lawrence County, Tennessee. In the course of such treatment, Defendants' saline solution was used to clean her wounds.
- 16. On or about April 30, 2024, Plaintiff presented to Ms. Tiffany Woodard, R.N., W.C.C., for a wound care consultation and treatment. Upon arrival, Plaintiff complained of right lower leg venous ulcers and venous insufficiency.
- 17. Plaintiff underwent a culture of her wounds, which revealed a *Vibrio Vulnificus* infection.
- 18. After a clinical examination, Ms. Woodard performed selective debridement of the wounds on Plaintiff's right lateral lower leg and right lateral inferior lower leg, administered dressing and gauze, applied compression using ACE wrap, and applied an Unna boot. Ms. Woodard recommended Plaintiff undergo home health services for skilled nursing and instructed her to return for a follow-up until home health had been confirmed.
- 19. On or about May 7, 2024, Plaintiff presented to Ms. Sara Smith, F.N.P., for wound care treatment. Upon arrival, Plaintiff remained symptomatic for her previously stated complaints. After a clinical examination, Ms. Smith treated Plaintiff's right lateral lower leg wound and her right lateral inferior lower leg wound was cleaned and foam dressing, rolled gauze, and applied compression using Ace Wrap was applied as well as an Unna Boot. Ms. Smith recommended IV antibiotics and PICC line placement to treat Plaintiff's bacterial infection.

- 20. On or about May 9, 2024, Plaintiff presented to Ms. Amber Rowland, R.N., at which time she underwent an antimicrobial PICC line placement and received her first dose of Zerbaxa.
- 21. On or about May 10, 2024, Plaintiff was attended to by Ms. Renee Warren, R.N., for a home health evaluation and treatment. During the visit, Plaintiff complained of a diabetic ulcer on her right lower extremity and sleeping difficulties. After a clinical examination, Ms. Warren administered Zerbaxa, performed wound care, and recommended a treatment plan that consisted of, but was not limited to, the following: skilled nursing visits and wound care.
- 22. On or about May 14, 2024, Plaintiff was attended by Ms. Warren for home health care. Upon arrival, Plaintiff complained of a diabetic ulcer on her right lower extremity and nausea, diarrhea, brain fogginess, and headaches as side effects from the intravenous antibiotic. Plaintiff received wound care.
- 23. Over the next several months, Plaintiff continued to suffer from complications related to and attempt treatment of the wound infection. And on or about August 30, 2024, Plaintiff returned to Ms. Woodward for wound care treatment. Upon arrival, Plaintiff complained of a right lateral lower leg chronic full-thickness venous ulcer. After a clinical examination, Ms. Woodward administered wound care and recommended a follow-up appointment be scheduled.
- 24. The following month, on or about September 24, 2024, Plaintiff again returned to Ms. Woodward for further wound care treatment. Upon arrival, Plaintiff complained of right lower leg venous ulcer lower leg edema and lymphedema and venous stasis dermatitis. After a complete and thorough physical examination, Ms. Woodward again administered wound care and noted that Plaintiff's wound continued to be macerated, stated that she would be considered for palliative

care for wound healing, and recommended keeping her dressing clean, dry, and intact and returning the next week for a follow-up appointment.

- 25. On or about September 27, 2024, Plaintiff was attended to by Ms. Kana Hold, R.N., for a home health progress examination due to her worsening lower extremity wounds. Plaintiff received wound care and remained symptomatic for pain in her right leg.
- 26. On or about October 4, 2024, Plaintiff presented to the emergency room for emergent treatment and care due the worsening condition of her leg wounds. Upon arrival, Plaintiff complained of her right lower extremity wound. After completing a physical examination, the attending emergency physician administered wound care and discharged Plaintiff with prescriptions for Cefpodoxime and Clindamycin and recommended she follow up with her primary care provider and wound care.
- 27. Testing of Defendants' Saline Solution samples still in Plaintiff's custody and control demonstrated that the subject product was contaminated with *Vibrio vulnificus*. Plaintiff's encounter with the subject product resulted in her sustaining significant personal injuries and other damages.
- 28. Plaintiff and her health care providers relied upon the marketing and statements of Defendants that their products were safe and effective for their intended use (treating Plaintiff's wounds), that they would be sterile, and that they would not contain dangerous bacterial contamination.
- 29. But for her use of the inherently dangerous contaminated product, Plaintiff's wound complications would not have been as severe nor would her healing process have been as extended and her damages as significant.

30. As a direct and proximate result of the defective and contaminated Saline Solution and the wrongful acts and omissions of the Defendants as alleged herein, Plaintiff was injured and caused various physical, mental, and emotional injuries and damages, which continue to this day and are reasonably foreseeable in the future.

FRAUDLENT CONCEALMENT

- 31. Plaintiff incorporates the preceding paragraphs as if set out fully herein.
- 32. Defendants' failure to document or follow up on the known defects in its product, and concealment of known defects, constitutes fraudulent concealment that equitably tolls applicable statutes of limitation.
- 33. Defendants are estopped from relying on the statute of limitations defense because Defendants actively concealed the defects, suppressing reports, failing to follow through on regulatory requirements, and failing to disclose known defects to physicians. Instead of revealing the defects, Defendants continued to represent their Saline Solutions as safe for their intended use.
- 34. Defendants are and were under a continuing duty to disclose the true character, quality, and nature of risks and dangers associated with their Saline Solutions and their contaminated nature to each individual user. Due to Defendants' concealment of the true character, quality, and nature of their Saline Solutions, Defendants are estopped from relying on any statute of limitations defense.
- 35. Defendants furthered this fraudulent concealment through a continued and systematic failure to disclose information to Plaintiff, Plaintiff's healthcare Providers, and the public. Through information and belief, even the FDA recalls fail to fully identify the scope of Defendants' contaminated products or the risks associated with the same.

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36. Defendants' acts before, during and/or after the act causing Plaintiff's injury prevented Plaintiff from discovering the injury or potential the cause of the injury until no earlier than April 30, 2024.

37. Defendants' conduct, as described in this Complaint, amounts to conduct purposely committed, which Defendants must have realized was dangerous, heedless, reckless, and without regard to the consequences or Plaintiff's rights and safety.

38. Defendants' conduct, as described in this Complaint, also amounts to a continuing tort, and continues up through and including the date of the filing of Plaintiff's Complaint.

DISCOVERY RULE AND TOLLING

- 39. Plaintiff incorporates the preceding paragraphs as if set out fully herein.
- 40. Despite diligent investigation by Plaintiff into the cause of her injuries, the nature of her injuries and damages, her relationship to the Saline Solution product was not discovered, and through reasonable care and diligence could not have discovered until at least April 30, 2024. Therefore, under appreciate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.
- 41. Plaintiff did not learn of Defendants' wrongful conduct until a time within the applicable statute of limitations. Furthermore, in the existence of due diligence, Plaintiff could not have reasonably discovered the Defendant's wrongful conduct, including, but not limited to, the defective development, production, sterilization, and packaging of the product, until a date within the statute of limitations. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the statutory limitations period.

COUNT I: NEGLIGENCE PURSUANT TO TENNESSEE PRODUCTS LIABILITY ACT

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Tenn. Code Ann. §§ 29-28-101, et seq.

- 42. Plaintiff incorporates the preceding paragraphs as if set out fully herein.
- 43. The Defendants owed Plaintiff a duty to exercise reasonable care when developing, producing sterilizing, packaging, marketing, advertising, distributing, selling, conducting postmarket surveillance of the Saline Solution, and recruitment, instruction, and training of patients and medical professionals of its use.
- 44. The Defendants failed to exercise due care under the circumstances and therefore breached this duty by:
 - Failing to properly and thoroughly produce the Saline Solution with bacterial contamination before releasing the product to market, and/or failing to implement feasible safety improvements;
 - b. Failing to properly and thoroughly sterilize the product to prevent contamination;
 - c. Failing to properly and thoroughly package the product to prevent contamination;
 - d. Failing to conduct sufficient post-market testing and surveillance of the product to ensure it was not contaminated prior to use by patients and/or medical personnel;
 - e. Failing to comply with state and federal regulations concerning the study, testing, design, development, production, sterilization, packaging, inspection, advertisement, marketing, promotion, distribution, and/or sale of the Saline Solution;

- f. Designing, producing, sterilizing, packaging, marketing, advertising, distributing, and selling the Saline Solution to consumers, including Plaintiff and her medical professionals, without an adequate warning of the significant and dangerous risks of the Saline Solution, including, but not limited to, its propensity to cause infection, and without proper instructions to avoid the harm which could foreseeably occur as a result of using the product;
- g. Failing to exercise due care when advertising and promoting the Saline Solution; and
- h. Negligently continuing to manufacture, produce, sterilize, package, market, advertise, and distribute the Saline Solution after Defendants knew or should have known of its associated contamination dangers and/or adverse effects.
- 45. As a direct and proximate result of the defective Saline Solution and the wrongful acts and omissions of the Defendants as alleged herein, Plaintiff was injured due to the use of the Saline Solution, which caused various physical, mental, and emotional injuries and damages. Accordingly, Plaintiff seeks compensatory damages.
- 46. In performing the foregoing acts, omissions, and misrepresentations, Defendants acted grossly negligent, fraudulently, and with malice so as to justify an award of punitive and/or exemplary damages.

COUNT II: STRICT PRODUCTS LIABILITY – DESIGN DEFECT PURSUANT TO TENNESSEE PRODUCTS LIABILITY ACT

Tenn. Code Ann. §§ 29-28-101, et seq.

- 47. Plaintiff incorporates the preceding paragraphs as if set out fully herein.
- 48. Defendants supplied, manufactured, sold, distributed and/or otherwise placed into

the stream of commerce the Saline Solution used on/by Plaintiff.

- 49. The Saline Solution used on/by Plaintiff was not reasonably safe for its intended use and was defective with respect to its design, production, and development.
- 50. The product was defective in its design, production, and development in that when it left the hands of Defendants, it was not safe for its anticipated use and safer, more reasonable alternative designs existed that could have been utilized by Defendants.
- 51. The Saline Solution was in a defective condition at the time that it left the possession or control of Defendants.
- 52. A reasonably prudent medical product company would not have placed the Saline Solution with its defective properties into the stream of commerce.
- 53. The Saline Solution was defectively design, production, and development when supplied, sold, distributed and/or otherwise placed into the stream of commerce and when it was used on/by Plaintiff.
- 54. The Saline Solution was unreasonably dangerous, taking into consideration the utility of said product and the risks involved in its use. The foreseeable risks associated with the design, production, and development of the contaminated product were more dangerous than a reasonably prudent consumer such as Plaintiff and/or her physician would expect when the product was used for its normal and intended purpose.
- 55. The Saline Solution reached Plaintiff and her medical professionals without any substantial change in the condition in which it was supplied, distributed, sold and/or otherwise placed into the stream of commerce.
 - 56. The Saline Solution failed to perform as safely as an ordinary consumer and/or her

physician would expect when used as intended or when used in a manner reasonably foreseeable by the manufacturer, and the risks and dangers of the Saline Solution outweigh its benefits.

- 57. The design defects in the Saline Solution were not known, knowable and/or reasonably apparent to Plaintiff and/or her medical professionals or discoverable upon any reasonable examination.
- 58. The Saline Solution was used in the manner in which it was intended to be used and by Defendants pursuant to the instructions for use and the product specifications provided by Defendants.
- 59. Defendants are strictly liable to Plaintiff for designing, producing, sterilizing, packaging, manufacturing, marketing, labeling, and selling a defective product.
- 60. As a direct and proximate result of Defendants' wrongdoing alleged in Count II, Plaintiff suffered severe pain, suffering, disability, impairment, emotional distress, loss of enjoyment of life, loss of care, comfort, and consortium, and economic losses and damages including, but not limited to medical expenses, lost income, and other special damages. Accordingly, Plaintiff seeks compensatory damages.
- 61. In performing the foregoing acts, omissions, and misrepresentations, Defendants acted grossly negligent, fraudulently, and with malice so as to justify an award of punitive and/or exemplary damages.

COUNT III: STRICT PRODUCTS LIABILITY – FAILURE TO WARN PURSUANT TO TENNESSEE PRODUCTS LIABILITY ACT Tenn. Code Ann. §§ 29-28-101, et seq.

- 62. Plaintiff incorporates the preceding paragraphs as if set out fully herein.
- 63. Defendants designed, set specifications, manufactured, prepared, compounded,

assembled, processed, produced, sterilized, packaged, marketed, labeled, distributed, and sold the Saline Solution, including the one used on/by Plaintiff, into the stream of commerce and in the course of same, directly advertised and marketed the product to consumers or persons responsible for consumers, and therefore had a duty to warn of the risk of harm associated with the use of the product and to provide adequate instructions on the safe and proper use of the product.

- 64. At the time Defendants designed, developed, manufactured, produced, sterilized, packaged, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the Saline Solution into the stream of commerce, the product was defective and presented a substantial danger to users when put to its intended and reasonably anticipated use.
- 65. Defendants failed to adequately warn of the product's known or reasonably scientifically knowable dangerous propensities and further failed to adequately provide instructions on its safe and proper use given the unreasonableness of its contaminated nature.
- 66. Defendants knew or should have known at the time they manufactured, developed, produced, sterilized, packaged, labeled, distributed and sold the Saline Solution that was used on/by Plaintiff that it posed a significant and higher risk than other similar products of causing serious injuries.
- 67. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the Saline Solution; no reasonable health care provider, including Plaintiff's, and no reasonable patient would have used the product in the manner directed, had those facts been made known.
- 68. The warnings, labels, and instructions provided by the Defendants at all times relevant to this action, are and were inaccurate, intentionally misleading, and misinformed and

misrepresented the risks and benefits and lack of safety and efficacy associated with the product.

- 69. The health risks associated with the product as described herein are of such a nature that ordinary consumers would not have readily recognized the potential harm.
- 70. The Saline Solution, which was designed, manufactured, developed, sterilized, packaged, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold into the stream of commerce by Defendants, was defective at the time of release into the stream of commerce due to inadequate warnings, labeling and/or instructions accompanying the product.
- 71. When Plaintiff used the product, Defendants failed to provide adequate warnings, instructions, or labels regarding the severity and extent of health risks posed by it, as discussed herein.
- 72. Defendants intentionally underreported the number and nature of adverse events associated with contamination of the products to Plaintiff's health care providers, as well as the FDA.
- 73. Neither Plaintiff nor her health care providers knew of the substantial danger associated with the intended and foreseeable use of the product as described herein.
- 74. Plaintiff and her health care providers used the Saline Solution in a normal, customary, intended, and foreseeable manner.
- 75. Upon information and belief, the defective and dangerous condition of the product, including the one used on/by Plaintiff, existed at the time they were manufactured, developed, produced, sterilized, packaged, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold by Defendants to distributors and/or healthcare professionals or organizations.
 - 76. Upon information and belief, the product used on/by Plaintiff was in the same

condition as when it was manufactured, developed, produced, sterilized, packaged, inspected, marketed, labeled, promoted, distributed and sold by Defendants.

77. Defendants' lack of sufficient warning and/or instructions was the direct and proximate cause of Plaintiff's serious physical injuries, and economic damages in an amount to be determined at trial. In other words, had Defendants provided adequate warnings, Plaintiff and her health care professionals would not have used the product.

78. As a direct and proximate result of defective Saline Solution and the wrongful acts and omissions of the Defendants as alleged herein, Plaintiff was injured due to the use of the Saline Solution, which caused Plaintiff various physical, mental, and emotional injuries and damages. Accordingly, Plaintiff seeks compensatory damages.

COUNT IV: BREACH OF IMPLIED WARRANTY PURSUANT TO TENNESSEE PRODUCTS LIABILITY ACT

Tenn. Code Ann. §§ 29-28-101, et seq.

- 79. Plaintiff incorporates preceding paragraphs as if set out fully herein.
- 80. Defendants impliedly warranted that the Saline Solution was merchantable and fit for the ordinary purposes for which it was intended.
- 81. When the Saline Solution was used on/by the Plaintiff, it was being used for the ordinary purposes for which it was intended.
- 82. The Plaintiff, individually and/or by and through her physician, relied upon Defendants' implied warranties of merchantability in consenting to have the Saline Solution used on/by her.
 - 83. Privity exists between Plaintiff because Plaintiff's physicians acted as Plaintiff's

purchasing agents in the subject transaction and/or because Plaintiff was a third-party beneficiary of the subject contract.

- 84. Plaintiff was the intended consumer of the product when Defendants made the warranties set forth herein, and such warranties were made to benefit Plaintiff as a patient and consumer.
- 85. Defendants breached these implied warranties of merchantability because the Saline Solution used on/by Plaintiff was neither merchantable nor suited for its intended uses as warranted in that the product varied from its intended specifications, which included, but are not limited to, variances in the following respects:
 - a. Defendants failed to properly and thoroughly produce the Saline Solution without bacterial contamination before releasing the product to market, and/or failed to implement feasible safety improvements;
 - b. Defendants failed to properly and thoroughly sterilize the product to prevent contamination;
 - c. Defendants failed to properly and thoroughly package the product to prevent contamination;
 - d. Defendants failed to conduct sufficient post-market testing and surveillance of the product to ensure it was not contaminated prior to use by patients and/or medical personnel;
 - e. Defendants failed to comply with state and federal regulations concerning the study, testing, design, development, production, sterilization, packaging, inspection, advertisement, marketing, promotion, distribution, and/or sale of the Saline Solution;

- f. Defendants failed to exercise due care when advertising and promoting the Saline Solution; and
- g. Defendants represented to Plaintiff and her physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defendants' Saline Solution was of merchantable quality and safe when used for its intended purpose meanwhile Defendant fraudulently withheld and concealed information about the substantial risks of serious injury associated with using Saline Solution;
- h. Defendant represented to Plaintiff and her physicians and healthcare providers that the Defendants' Saline Solution was safe, as safe as and/or safer than other alternative procedures and devices, meanwhile Defendant fraudulently concealed information, which demonstrated that the Saline Solution was not safe, as safe as or safer than alternatives and other products available on the market; and
- Defendants represented to Plaintiff and her physicians and healthcare providers that the
 Defendants' Saline Solution was more efficacious than other alternative products.

 Meanwhile Defendant fraudulently concealed information, regarding the true efficacy
 of the Saline Solution product.
- 86. Defendants' breaches of their implied warranties resulted in the use of an unreasonably dangerous and defective product, the Saline Solution, placing Plaintiff's health and safety in jeopardy.
- 87. The Saline Solution was sold to Plaintiff's health care providers for use in/on/by patients, such as Plaintiff.

- 88. As a direct and proximate result of the defective Saline Solution and the wrongful acts and omissions of the Defendants as alleged herein, Plaintiff was injured due to the use of the Saline Solution, which caused Plaintiff various physical, mental, and emotional injuries and damages. Accordingly, Plaintiff seeks compensatory damages.
- 89. Upon information and belief, Plaintiff's healthcare providers sent notice to Defendants of the adverse event that occurred to Plaintiff and thus, the nonconformity of the Saline Solution, within a reasonable period of time following discovery of the breach of warranty and before suit was filed.

COUNT V: BREACH OF EXPRESS WARRANTY PURSUANT TO TENNESSEE PRODUCTS LIABILITY ACT

Tenn. Code Ann. §§ 29-28-101, et seq.

- 90. Plaintiff incorporates the preceding paragraphs as if set out fully herein.
- 91. Defendants through their officers, directors, agents, representatives, and written literature and packaging, and written and media advertisement, expressly warranted that the Saline Solution was safe and fit for use by consumers, was of merchantable quality, did not produce dangerous side effects, and was adequately tested and fit for its intended use.
- 92. The Saline Solution does not conform to the Defendants' express representations because it is not reasonably safe, has numerous serious side effects, and causes severe and permanent injury.
- 93. Defendants further breached express representations and warranties made to Plaintiff, her physicians and healthcare providers with respect to the Saline Solution used on/by Plaintiff in the following respects:

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- a. Defendant represented to Plaintiff and her physicians and healthcare providers through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions among other ways that the Defendants' Saline Solution was safe, meanwhile Defendant fraudulently withheld and concealed information about the substantial risks of serious injury associated with using Saline Solution;
- b. Defendant represented to Plaintiff and her physicians and healthcare providers that the Defendants' Saline Solution was as safe and/or safer than other alternative products then on the market, meanwhile Defendant fraudulently concealed information that demonstrated that Saline Solution was not safer than alternative therapies and products available on the market; and
- c. Defendant represented to Plaintiff and her physicians and healthcare providers that the Defendants' Saline Solution was more efficacious than other alternative procedures, therapies and/or products. Meanwhile, Defendants fraudulently concealed information, regarding the true efficacy and risks of Saline Solution.
- 94. The Saline Solution does not conform to the Defendants' express representations because it is not reasonably safe, was not sterile, was contaminated, has numerous serious side effects, and causes severe and permanent injury.
- 95. At all relevant times, the Saline Solution did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.
 - 96. Plaintiff, her physicians, and the medical community reasonably relied upon the

Defendants' express warranties for the Saline Solution.

97. Privity exists between Plaintiff because Plaintiff's physicians acted as Plaintiff's

purchasing agents in the subject transaction and/or because Plaintiff was a third-party beneficiary

of the subject contract.

98. Plaintiff was the intended consumer of the product when Defendant made the

warranties set forth herein, and such warranties were made to benefit Plaintiff as a patient and

consumer.

99. At all relevant times, the Saline Solution was used on Plaintiff's

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

100. Plaintiff and Plaintiff's physicians, by the use of reasonable care, could not have

discovered the breached warranty and realized its danger prior to its use on/by Plaintiff.

101. As a direct and proximate result of the defective Saline Solution and the wrongful

acts and omissions of the Defendants are alleged herein, Plaintiff was injured due to the use of the

Saline Solution, which caused Plaintiff various physical, mental, and emotional injuries and

damages. Accordingly, Plaintiff seeks compensatory damages.

102. Upon information and belief, Plaintiff's healthcare providers sent notice to

Defendants of the adverse event that occurred to Plaintiff and thus, the nonconformity of the Saline

Solution, within a reasonable period of time following discovery of the breach of warranty and

before suit was filed.

COUNT VI: FRAUDULENT CONCEALMENT PURSUANT TO TENNESSEE

PRODUCTS LIABILITY ACT

Tenn. Code Ann. §§ 29-28-101, et seq.

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- 103. Plaintiff incorporates the preceding paragraphs as if set out fully herein.
- 104. Defendants made false statements and representations to Plaintiff and her healthcare providers concerning the Saline Solution product used on/by Plaintiff.
- 105. Defendants engaged in and fraudulently concealed information with respect to the Saline Solution in the following respects:
 - a. Defendants represented through the labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that the Saline Solution was safe and fraudulently withheld and concealed information about the substantial risks of using the Saline Solution, including but not limited to, its purported sterile condition and lack of contamination;
 - b. Defendants represented that the Saline Solution was safer than other alternative products and fraudulently concealed information which demonstrated that the Saline Solution was not safer than alternatives available on the market;
 - Defendants concealed that they knew these products were not sterile and could be contaminated;
 - d. Defendants knew that neither Medicare, Medicaid, nor most private insurance entities offer reimbursement for medical devices which aren't approved or cleared by the FDA or which do not conform to their intended use; and
 - e. That frequency of these failures and the severity of injuries were substantially worse than had been reported.
 - 106. Defendants had knowledge that the representations they made concerning the

Saline Solution, as stated above, were false.

- 107. Defendants had sole access to material facts concerning the dangers and unreasonable risks of the Saline Solution.
- 108. The concealment of information by the Defendants about the risks of the Saline Solution was intentional.
- 109. The concealment of information and the misrepresentations about the Saline Solution was made by the Defendants with the intent that Plaintiff's health care providers and Plaintiff rely upon them.
- 110. Plaintiff and her physicians relied upon the representations and were unaware of the substantial risks of the Saline Solution which the Defendants concealed from the public, including Plaintiff and her physicians.
- 111. As a direct and proximate result of the defective Saline Solution and the wrongful acts and omissions of the Defendants as alleged herein, Plaintiff was injured due to the use of the Saline Solution, which caused Plaintiff various physical, mental, and emotional injuries and damages. Accordingly, Plaintiff seeks compensatory damages.
 - 112. The Defendants acted with oppression, fraud, and malice towards Plaintiff.
- 113. Had Defendants not concealed this information, neither Plaintiff's nor her health care providers would have consented to using the product in Plaintiff.

COUNT VII: TENNESSEE CONSUMER PROTECTION ACT OF 1977 Tenn. Code Ann. § 47-18-101, et seq.

- 114. Plaintiff incorporates the preceding paragraphs as if set out fully herein.
- 115. Plaintiff purchased the Saline Solution, and the product was intended for personal

use.

- 116. The acts and practices engaged in by Defendants as outlined above constitute unlawful, unfair, and/or fraudulent business practices in violation of the Tennessee Consumer Protection Act of 1977. T.C.A. § 47-18-101, et seq.
- 117. Defendants engaged in unlawful practices including deception, false promises, misrepresentation, and/or the concealment, suppression, or omission of material facts in connection with the sale, distribution, and/or advertisement of the Saline Solution in violation of the Tennessee Consumer Protection Act of 1977.
- 118. Plaintiff purchased the Saline Solution, a product that was falsely represented as having certain characteristics and benefits it did not have, *inter alia*, that it was reasonably safe for use, as further set forth above, in violation of the Tennessee Consumer Protection Act of 1977.
- 119. Defendants further knowingly or recklessly engaged in unfair, unconscionable, deceptive, deliberately misleading, false, and/or fraudulent and deceptive acts and practices, all in violation of the Tennessee Consumer Protection Act of 1977, and as further described herein, which created a likelihood of confusion or misunderstanding on Plaintiff's part with respect to the Saline Solution she purchased, including, but not limited to, misrepresenting that the Saline Solution was reasonably safe for use and failing to adequately disclose the substantial risk of infection, and harm the product entailed given the large number of adverse events Defendants knew or should have been aware of but did not adequately disclose to Plaintiff.
- 120. Defendants' practices were likely to mislead consumers who acted reasonably to their detriment in purchasing the product based on Defendants' representations that it was reasonably safe for use when it in fact was not and had a higher risk of infection due to its defective

design.

- 121. Defendants intended for Plaintiff, Plaintiff's physicians, and other consumers to rely on their deceptive practices and representations in order to continue selling and manufacturing the Saline Solution.
- 122. As a result of Defendants' conduct, Plaintiff suffered actual damages in that the product she purchased was misrepresented and worth far less than the product she thought she had purchased, had Defendants' representations been true.

PUNITIVE DAMAGES PURSUANT TO

Tenn. Code Ann. §§ 29-39-104

Defendants' intentional, willful, knowing, fraudulent, malicious acts, omissions, and conduct, and their complete and total reckless disregard for the public safety and welfare. Defendants intentionally and fraudulently misrepresented facts and information to both the healthcare community and the general public, including Plaintiff and her health care providers, by making intentionally false and fraudulent misrepresentations about the safety and efficacy of the Saline Solution. Defendants intentionally concealed the true facts and information regarding the serious risks of harm associated with the implantation of said product, and intentionally downplayed the type, nature, and extent of the adverse side effects of being implanted with the product, despite Defendants' knowledge and awareness of the serious and permanent side effects and risks associated with use of same. Defendants further intentionally sought to mislead health care providers and patients, including Plaintiff and her health care providers, regarding the cause of failures of the product.

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124. Defendants had knowledge of, and were in possession of evidence demonstrating that, the Saline Solution caused serious physical side effects. Defendants continued to market said product by providing false and misleading information with regard to the product's safety and efficacy to the regulatory agencies, the medical community, and consumers of the product, notwithstanding Defendants' knowledge of the true serious side effects of the Saline Solution, Defendants failed to provide accurate information and warnings to the healthcare community that would have dissuaded physicians from using the Saline Solution and consumers from agreeing to using the Saline Solution, thus depriving physicians and consumers from weighing the true risks against the benefits of prescribing and implanting the Saline Solution.

125. As a direct, proximate, and legal result of Defendants' acts and omissions a described herein, and Plaintiff's implantation with Defendants' defective product, Plaintiff suffered the injuries and damages described in this Complaint.

PRAYER

WHEREFORE, Plaintiff prays for judgment against each of the Defendants as follows:

- a. Judgment be entered against all Defendant on all causes of action of this Complaint;
- b. Plaintiff be awarded her full, fair, and complete recovery for all claims and causes of action relevant to this action;
- c. Plaintiff be awarded general damages according to proof at the time of trial;
- d. Plaintiff be awarded damages, including past, present, and future, medical expenses according to proof at the time of trial;
- e. Awarding pre-judgment and post-judgment interest to the Plaintiff;
- f. Awarding the costs and the expenses of this litigation to the Plaintiff;

g. For such other and further relief as the court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury on all issues.

Dated: April 17, 2025 Respectfully submitted,

/s/ Hamilton Jordan
Hamilton Jordan
Jon C. Conlin (to be admitted Pro Hac Vice)
Cory Watson, P.C.
2131 Magnolia Avenue South
Birmingham, AL 35205
Phone: (205) 328-2200
HJordan@CoryWatson.om
JConlin@CoryWatson.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 do	ocket sheet. (SEE INSTRUC	CTIONS ON NEXT PAGE O	F THIS FO			
I. (a) PLAINTIFFS				DEFENDANTS		
Jennifer Wilson				Nurse Assist, LLC, d/b/a McKesson and Stericare Solutions		
(b) County of Residence of First Listed Plaintiff Lawrence County, (EXCEPT IN U.S. PLAINTIFF CASES)			TN_	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.		
Hamilton Jordan	Address, and Telephone Number, Cory Watson, P.C AL 35205, 205-328-	., 2131 Magnolia <i>i</i>	Ave	Attorneys (If Known)		
II. BASIS OF JURISD	ICTION (Place an "X" in	One Box Only)			RINCIPAL PARTIES	(Place an "X" in One Box for Plaintiff
U.S. Government Plaintiff	U.S. Government Not a Party)			(For Diversity Cases Only) PT en of This State		
2 U.S. Government Defendant				en of Another State	of Business Ir	n Another State
IV NATURE OF CHI				en or Subject of a reign Country		6 6
IV. NATURE OF SUIT		nly) ORTS	l EC	ORFEITURE/PENALTY	Click here for: Nature of BANKRUPTCY	OTHER STATUTES
110 Insurance 120 Marine 130 Miller Act 140 Negotiable Instrument 150 Recovery of Overpayment & Enforcement of Judgment 151 Medicare Act 152 Recovery of Defaulted Student Loans (Excludes Veterans) 153 Recovery of Overpayment of Veteran's Benefits 160 Stockholders' Suits 190 Other Contract 195 Contract Product Liability 196 Franchise REAL PROPERTY 210 Land Condemnation 220 Foreclosure 230 Rent Lease & Ejectment 240 Torts to Land 245 Tort Product Liability 290 All Other Real Property	PERSONAL INJURY 310 Airplane 315 Airplane Product Liability 320 Assault, Libel &	PERSONAL INJURY 365 Personal Injury - Product Liability A 367 Health Care/ Pharmaceutical Personal Injury Product Liability 368 Asbestos Personal Injury Product Liability PERSONAL PROPERT 370 Other Fraud 371 Truth in Lending 380 Other Personal Property Damage 385 Property Damage Product Liability PRISONER PETITION Habeas Corpus: 463 Alien Detainee 510 Motions to Vacate Sentence 530 General 535 Death Penalty Other:	7	LABOR O Fair Labor Standards Act O Labor/Management Relations Railway Labor Act Family and Medical Leave Act O Other Labor Litigation Employee Retirement Income Security Act IMMIGRATION Note The Medical Act O Naturalization Application Other Labor Litigation	422 Appeal 28 USC 158	375 False Claims Act 376 Qui Tam (31 USC 3729(a)) 400 State Reapportionment 410 Antitrust 430 Banks and Banking 450 Commerce 460 Deportation 470 Racketeer Influenced and Corrupt Organizations 480 Consumer Credit (15 USC 1681 or 1692) 485 Telephone Consumer Protection Act 490 Cable/Sat TV 850 Securities/Commodities/
	noved from 3 te Court Cite the U.S. Civil Sta 28 U.S.C. §1332(a) Brief description of ca	Appellate Court atute under which you are	4 Reins Reop		District Litigation Transfer	on - Litigation -
VII. REQUESTED IN COMPLAINT:	Product Liability Saline CHECK IF THIS UNDER RULE 2	IS A CLASS ACTION	D	EMAND \$	CHECK YES on	y if demanded in complaint: D: X Yes No
VIII. RELATED CASI IF ANY	E(S) (See instructions):	JUDGE			DOCKET NUMBER	
DATE		SIGNATURE OF ATT	ORNEY (OF RECORD		
4/17/2025		/s/ Hamilton Jordan				
FOR OFFICE USE ONLY						

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

- **L(a) Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
- (b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
- (c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".
- II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.

 United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here. United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.

 Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.

 Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; NOTE: federal question actions take precedence over diversity cases.)
- **III. Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.
- **IV. Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.
- V. Origin. Place an "X" in one of the seven boxes.
 - Original Proceedings. (1) Cases which originate in the United States district courts.

Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date. Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.

Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket. **PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7.** Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.

- VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service.
- VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.

 Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.

 Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.
- VIII. Related Cases. This section of the JS 44 is used to reference related cases, if any. If there are related cases, insert the docket numbers and the corresponding judge names for such cases.

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