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**UNITED STATES DISTRICT COURT**

**CENTRAL DISTRICT OF CALIFORNIA**

HRAYR SHAHINIAN, M.D., F.A.C.S., an individual; on behalf of himself and all others similarly situated,

Plaintiffs,

vs.

KIMBERLY-CLARK CORPORATION, a Delaware Corporation,

Defendants.

CASE NO.: 14-CV-08390

**NATIONWIDE AND CALIFORNIA CLASS ACTION COMPLAINT FOR:**

1. **FRAUDULENT CONCEALMENT/NON-DISCLOSURE;**
2. **FRAUD (AFFIRMATIVE MISREPRESENTATIONS);**
3. **NEGLIGENT MISREPRESENTATION**
4. **UNFAIR BUSINESS PRACTICES (Cal. Bus. & Prof. Code § 17200 *et seq.*)**
5. **FALSE ADVERTISING (Cal. Bus. & Prof. Code § 17500 *et seq.*)**

**DEMAND FOR JURY TRIAL**

Plaintiff Hrayr Shahinian, M.D., F.A.C.S., on behalf of himself and a class of all others similarly situated, hereby alleges as follows:

## I. BACKGROUND

1. This action is brought against Kimberly-Clark Corporation for marketing and selling medical gowns represented to provide the highest level of liquid barrier protection from the transfer of bodily fluids, bacteria, and infection between a patient and health care professional when, in reality, Kimberly-Clark has known since at least as early as 2013 that these gowns failed industry standard tests, are unsafe and do not meet relevant standards. During those tests, ASTM F1671 tests of numerous random samples taken from multiple separate manufacturing lots were conducted. In each of the tests, the High Performance Gowns failed at rates that greatly exceeded failure rates acceptable for satisfying industry standards, with many of the gowns experiencing catastrophic failures. Among other things, the tests revealed that the gowns allowed liquid and bacterial and viral pathogens to penetrate the gowns. And yet from at least as early as 2013 to the present, Kimberly-Clark has continued to sell these gowns and misrepresent to its customers and the general public that these gowns are impermeable and are effective when treating patients with serious diseases such as Ebola, all the while knowing that they are unsafe and pose great risk of bodily harm and possibly death to patients and health care professionals worldwide. Kimberly Clark's recklessness and indifference as to the fact that it is responsible for placing patients and health care professionals at great and unnecessary risk of infection and bodily harm as described below is nothing short of astonishing and utterly reprehensible.

## II. PARTIES

2. Plaintiff Hrayr Shahinian, M.D., F.A.C.S., ("Plaintiff" or "Shahinian") is a citizen of the State of California, and resident of Los Angeles County. Shahinian is a medical doctor and experienced surgeon who practices and resides in the County of Los

Angeles, State of California, within the Central District. He is a skull base surgeon and founder of the Skull Base Institute (SBI). Since 1994, he has pioneered numerous new endoscopic surgical techniques to treat a variety of skull base disorders and is nationally and internationally recognized as one of the first surgeons in the world to use and pioneer endoscopic skull base surgery. He is Board Certified by the American Board of Surgery and has been licensed to practice in California since 1996. He completed his undergraduate studies at the American University of Beirut in 1981 and earned his M.D. in 1985. He earned both degrees with distinction and has been an active member of the honor medical society, Alpha Omega Alpha. In 1986, Dr. Shahinian was recruited to Vanderbilt University Medical Center, where he completed an internship and residency in general surgery. In 1991, Dr. Shahinian went to New York University's Institute of Reconstructive Plastic Surgery, the premier craniofacial program in the nation where he completed a two-year fellowship in plastic and reconstructive surgery. Thereafter, in 1993, he completed a fellowship in skull base surgery and neurotology in the Department of Head and Neck Surgery in Zurich, Switzerland under the tutelage of Professor Ugo Fisch, the preeminent skull base surgeon in the world at the time. In 1994, Dr. Shahinian completed a second fellowship, in craniofacial surgery, at New York University. He was certified by the American Board of Surgery in 1992, recertified in 2003 and 2014, and is a Fellow of the American College of Surgeons since 2002. From 1994-1996, Dr. Shahinian served as an Assistant Professor of Surgery and Neurosurgery at the State University of New York at Stonybrook, during which time he was also Co-Director (1994-1995), and then Director (1995-1996) of the University's Skull Base Institute. In 1996, Dr. Shahinian was recruited by Cedars-Sinai Medical Center to establish and head its Division of Skull Base Surgery and to direct its Skull Base Institute. Dr. Shahinian accepted the offer, relocated to California and was instrumental in establishing what has become one of the country's largest practices specializing in minimally-invasive endoscopic skull base and brain tumor surgery: The Skull Base Institute (SBI) in Los Angeles.

Neurosurgeons from the United States as well as Barcelona, Marseilles, Brussels, Cairo, Kiev, Rome and Czech republic have travelled to Dr. Shahinian for observation and training in Skull Base Surgery. Patients from around the world and most of the 50 states also routinely travel to Los Angeles to be treated by Dr. Shahinian.

3. Dr. Shahinian has received many awards for his work in skull base surgery and has shared his experience and expertise in numerous journal articles, textbook chapters, and national and international presentations. He is also the author of the textbook, "Endoscopic Skull Base Surgery," which was published by Humana Press in 2009. Dr. Shahinian holds a number of patents and has thrice received the National Aeronautics and Space Administration (NASA) Innovation Award (in 2008, 2011 and 2012) for his work in the field of advanced medical technology.

4. In the course of his practice within the Central District, Dr. Shahinian has made use of the medical gowns manufactured and sold by Defendant Kimberly-Clark Corporation that are at issue in this lawsuit.

5. Defendant Kimberly-Clark Corporation ("Defendant," "Kimberly-Clark," or "KC") is a Delaware corporation with its principal executive offices located in Dallas, Texas. KC describes itself as a global company focusing on leading the world in essentials for a better life through product innovation and building its personal care, consumer tissue, K-C Professional, and health care brands. KC is principally engaged in the manufacturing and marketing of a wide range of products mostly made from natural or synthetic fibers using advanced technologies in fibers, nonwovens, and absorbency. KC owns several well-recognized consumer brands in the field of personal care and tissues, including, among others, Huggies, Pull-Ups, Kotex, Depend, Kleenex, Scott, Cottonelle, Viva, and other brand names.

6. Among its business segments, KC operates a health care segment, which it describes as providing "essentials that help restore patients to better health and improve the quality of patients' lives." In 2013, KC reported net sales of over $1.6 billion from its health care segment alone. This segment is focused on the sale of surgical and

infection prevention products for the operating room and other medical supplies, and medical devices focused on pain management, respiratory, and digestive health. KC describes itself as "a global leader in education to prevent healthcare-associated infections." KC's health care products are sold under the "Kimberly-Clark" and "ON-Q" brand names. Its health care products include medical exam gloves, facial masks and respirators, and surgical drapes and gowns. According to its 2013 Annual Report, KC sells its products to, among other entities, "health care establishments and high volume public facilities." On information and belief, during all relevant times, KC's market share of the surgical gown market at issue in this lawsuit exceeded 50%.

7. The true names and capacities of defendants DOES 1 through 100, inclusive, whether individual, plural, corporate, partnership, associate or otherwise, are not known to Plaintiff, who therefore sues said defendants by such fictitious names. Plaintiff is informed and believes and thereon alleges that each of the defendants designated herein as DOE are in some manner responsible for the acts and occurrences set forth herein. Plaintiff will seek leave of court to amend this Complaint to show the true names and capacities of defendants DOES 1 through 100, inclusive, as well as the manner in which each DOE defendant is responsible, when the same have been ascertained.

8. Plaintiff is informed and believes, and upon such basis alleges, that at all times herein mentioned, each of the Defendants herein was an agent, servant, employee, co-conspirator, partner, joint venturer, wholly owned and controlled subsidiary and/or alter ego of each of the remaining Defendants, and was at all times acting within the course and scope of said agency, service, employment, conspiracy, partnership and/or joint venture.

9. Defendants, and each of them, aided and abetted, encouraged and rendered substantial assistance in accomplishing the wrongful conduct and their wrongful goals and other wrongdoing complained of herein. In taking action, as particularized herein, to aid and abet and substantially assist the commission of these wrongful acts and other

wrongdoings complained of, each of the Defendants acted with an awareness of its primary wrongdoing and realized that its conduct would substantially assist the accomplishment of the wrongful conduct, wrongful goals, and wrongdoing.

## III. JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction over this action pursuant to the Class Action Fairness Act of 2005 and 28 U.S.C. § 1332 because there are over 100 members of the proposed class, at least one member of the proposed class has a different citizenship from a defendant and the total matter in controversy exceeds $5,000,000.

11. Venue is proper pursuant to 28 U.S.C. § 1391(b) & (c) because a substantial part of the events or omissions giving rise to the claim occurred in this judicial district, and because Defendant is subject to the Court's personal jurisdiction in this judicial district.

## IV. GENERAL ALLEGATIONS

12. As noted above, this action is brought against KC for marketing and selling medical/surgical gowns represented to be impermeable and to provide the highest level of protection from the transfer of bodily fluids, bacteria, and infection (i.e. Ebola) between patient and health care professional when in reality, Kimberly-Clark has known since at least as early as 2013 that these gowns failed industry tests and do not meet relevant standards.

13. From approximately 2011 to the present and continuing, KC and/or its distributors have promoted, marketed, and offered for sale to consumers, patients, doctors, clinics, and health care facilities worldwide surgical gowns sold under the name "MICROCOOL* Breathable High Performance Surgical Gowns" (hereafter, the "High Performance Gowns"). KC claims the High Performance Gowns provide the highest level of liquid barrier protection available. According to KC, the High

Performance Gowns are "AAMI Level 4" gowns. Indeed, in a press release introducing the High Performance Gowns, KC stated the gowns met the AAMI Level 4 Standard for liquid barrier protection and represented that the "gown helps prevent blood and other bodily fluids from penetrating through to the clinician's skin during any procedure and is specifically designed for the most demanding and fluid-intensive procedures." KC's Vice President of Global Sales and Marketing, Mr. John Amat, was quoted as saying "[t]he gown delivers surgeons and surgical staff a full spectrum of protection and the assurance of barrier integrity, allowing them to concentrate solely on patient care during long and stressful procedures and not on their risk of exposure." Attached as Exhibit A and incorporated herein by this reference is a true and correct copy of the press release dated May 16, 2011.

14. "AAMI" stands for the Association for the Advancement of Medical Instrumentation. AAMI developed the liquid barrier standard to assist healthcare personnel in the selection and use of surgical gowns, drapes, and other protective apparel. "AAMI Level 4" refers to the AAMI Level 4 Liquid Barrier Standard. AAMI performance levels range from 1 (least protective) to 4 (most protective). AAMI guidelines are a widely accepted system of classification for protective apparel and drapes based on liquid barrier performance. Therefore, by claiming the High Performance Gowns are AAMI Level 4 gowns, KC represents that they provide "the highest barrier protection rating available for gowns." KC further represents that the High Performance Gowns provide "Level 4" liquid barrier protection to "critical zones." "Critical zones," according to KC, include the front area of the gown from chest to knees and "the sleeves from the cuff to above the elbow." Attached as Exhibit B and incorporated herein by this reference is a true and correct copy of KC's full description of the High Performance Gowns, available on its website as of the filing date of this Complaint.

15. KC also represents that the High Performance Gowns are impermeable and meet and exceed: (a) ANSI/AAMI PB70; (b) ASTM F1670 and ASTM F1671 standards for resistance of materials used in protective clothing; and (c) the ASTM F1671 standard for bacteriophage penetration, as well as the European Norms (ENISO 22610) for resistance to wet microbial penetration.

16. ANSI/AAMI PB70 is set forth in a document published by AAMI entitled "Liquid barrier performance and classification of protective apparel and drapes intended for use in healthcare facilities." The document discusses a standard establishing minimum barrier performance requirements, a classification system, and associated labeling requirements for protective apparel, surgical drapes, and drape accessories intended for use in health care facilities.

17. ASTM F1670 and ASTM F1671 refer to standard test methods for the resistance of materials used in protective clothing to penetration by synthetic blood and blood-borne pathogens. The methods are based on a test method for measuring resistance of chemical protective clothing materials to penetration by liquids. They are normally used to evaluate specimens from individual finished items of protective clothing, including gowns and their seamed and other discontinuous regions, and individual samples of materials that are candidates for items of protective clothing.

18. From a regulatory perspective, KC knew at all relevant times that surgical gowns such as the High Performance Gowns at issue, are "class II" devices that fall under the classification of "Surgical apparel" pursuant to 21 C.F.R.§ 878.4040. The regulation describes surgical apparel as follows:

> Surgical apparel are devices that are intended to be worn by operating room personnel during surgical procedures **to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material**. Examples include surgical caps, hoods, masks, gowns, operating room shoes and shoe covers, and isolation masks and gowns. Surgical suits and dresses,

> commonly known as scrub suits, are excluded. 21 C.F.R. § 878.4040 (emphasis added).

19. Thus, in its submission to the FDA in connection with the gowns at issue, KC described the intended use of the gowns as follows:

> The Kimberly-Clark* MicroCOOL* Breathable High Performance Surgical Gowns, are sterile, single use surgical apparel intended to be worn by healthcare professionals to **help protect both the patient and the healthcare worker from the transfer of microorganisms, body fluids, and particulate matter**. The MicroCool Breathable High Performance Surgical Gowns meet the Level 4 requirements of the AAMI Liquid Barrier classifications. (emphasis added).

20. With respect to testing of the High Performance Gowns, KC represented to the FDA as follows:

> The Kimberly-Clark* MicroCool* Breathable High Performance Surgical Gown, has been tested in compliance with the requirements of Level 4 liquid barrier performance requirements of ANSI/AAMI PB70:2003 "*Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities.*" The MicroCool* Breathable High Performance Surgical Gown also meets the requirements of ASTM1671:2003 *Standard test method for resistance of materials used in protective clothing to penetration by blood-borne pathogens using Phi-X174 bacteriophage penetration as a test system.* The MicroCool* Breathable High Performance Surgical Gown also meets the requirements of Flame Resistant CPSC 1610 Class 1. The MicroCool* Breathable High Performance Surgical Gown has also been tested in compliance with the biocompatibility requirements of ISO 10993 for surface devices with limited contact with breached or compromised surfaces. All results of testing met acceptance criteria.

21. On information and belief, KC's representations concerning the level of protection of the High Performance Gowns are not true, and KC has known they are not true since at least 2013. Despite this knowledge, KC has not corrected its

representations, has not stopped selling the High Performance Gowns, has not recalled the High Performance Gowns it has already sold and/or caused to be placed in the distribution channel, has not reported the truth to the FDA, and has not alerted its customers that have purchased these gowns that the gowns were not and are not as represented. In fact, not only do the High Performance Gowns not *meet* the relevant standards for liquid barrier protection, KC has known since at least 2013 that its High Performance Gowns have *failed* the relevant tests, do not meet AAMI Level 4 and, thus, are at serious risk of causing physicians, health care professionals and patients to be unknowingly exposed to serious bacteria, viruses and illness, including but not limited to Ebola, and further causing such individuals to contract such diseases without warning.

22. In or around 2013 at the latest, KC became aware of failed test results for the High Performance Gowns. During those tests, ASTM F1671 tests of numerous random samples taken from multiple separate manufacturing lots were conducted. In each of the tests, the High Performance Gowns failed at rates that greatly exceeded failure rates acceptable for satisfying AAMI Level 4 standards, with many of the gowns experiencing catastrophic failures. Among other things, the tests revealed that the gowns allowed liquid and bacterial and viral pathogens to penetrate the gowns, thus placing physicians, health care professionals and patients at considerable risk.

23. As a result of these failed test results, KC knew that it could no longer honestly represent the High Performance Gowns as being "impermeable," of meeting AAMI Level 4, of meeting ASTM F1670 and F1671 testing standards, and/or of satisfying ANSI/AAMI PB70. It also knew that certain of its representations to the FDA regarding the gowns were false. KC also knew it should take immediate action to announce that the High Performance Gowns did not meet appropriate standards; recall the gowns; alert Federal, State and local governments and the FDA; alert physicians, health care professionals and patients worldwide; and undertake efforts to immediately cause the gowns to be removed from the shelves and distribution channels of health

care facilities and distributors worldwide. In short, KC knew as of 2013 at the latest and likely well over a year earlier, that the High Performance Gowns are not safe for the intended uses and place both patients *and* health care professionals at risk of serious infection and bodily harm.

24. However, instead of taking appropriate and immediate action to protect health care professionals and the public at large, KC did nothing of the sort. Kimberly Clark did not recall the gowns; did not alert Federal, State and local governments and the FDA; did not alert physicians, health care professionals and patients worldwide; and did not undertake efforts to immediately cause the gowns to be removed from the shelves and distribution channels of health care facilities and distributors worldwide. Indeed, on information and belief, in an effort to place their own monetary self interest ahead of the welfare of the general public and health care professionals worldwide, KC together with certain of its employees, executives, agents, distributors and others took affirmative steps to conceal, not disclose and cover-up their knowledge and purposely avoid and/or delay the disclosure of the problems with its gowns.

25. Moreover, despite its knowledge as described above, in recent public statements, KC has nevertheless represented that the High Performance Gowns are *safe to use in connection with patients suspected of contracting the Ebola virus*. KC's website states as follows:

> As concerns around the spread of the Ebola virus continue to grow, the number of inquiries we receive regarding recommendations for PPE [i.e., "Personal Protective Equipment"] and our plans for Pandemic Preparedness are growing in tandem. Therefore, we want to proactively provide you with guidance on preparing for a pandemic **as well as solutions for proper PPE**. We are providing you with a clinical Kimberly-Clark Ebola Virus Precautions Brief and a Kimberly-Clark Personal Protection Solutions guide as well as other resources to answer questions you have about the Ebola Virus Disease.

26. Below this statement on its website, KC shares a link inviting visitors to download the "Kimberly-Clark Personal Protection Solutions Guide," which advises health care facilities to use the High Performance Gowns in connection with treating patients who may be infected with the Ebola virus. The link to this list of KC products, which includes the High Performance Gowns, is also available on KC's letter to customers entitled the "Kimberly-Clark Pandemic Preparedness Customer Letter" dated August 14, 2014. Attached hereto as Exhibit C and incorporated herein by this reference is a true and correct copy of a page relating to Ebola preparedness available on KC's website. Attached hereto as Exhibit D is a true and correct copy of KC's August 14, 2014 letter posted on its website. Attached hereto as Exhibit E and incorporated herein by this reference is a true and correct copy of the list of KC "Personal Protective Equipment" products, which include the High Performance Gowns and which KC recommends in connection with the treatment of suspected or confirmed Ebola patients.

27. Further, on September 19, 2014, KC issued a document entitled "Kimberly-Clark Ebola Virus Disease (EVD) Precautions Brief." In this document, KC provides a list of recommendations for "Personal Protection" from the Ebola virus, as well as the use of "appropriate personal protective equipment (PPE)." With respect to surgical gowns, KC advises health care professionals to use "Level 4" gowns—the represented clearance level for the High Performance Gowns—for working with Ebola patients. Attached hereto as Exhibit F and incorporated herein by this reference is a true and correct copy of this document.

28. In short, despite knowing since at least 2013 that its High Performance Gowns failed industry tests and were at risk for allowing bodily fluid, bacteria, and other harmful matter to pass between patients and health care professionals, KC has recommended these gowns are safe for use in high-risk medical environments, including when treating Ebola. KC's recklessness and indifference to the prospect that it is responsible for placing patients and health care professionals at great and

unnecessary risk of infection and bodily harm is nothing short of astonishing and, more to the point, utterly reprehensible.

29. On October 10, 2014, AAMI issued a press release entitled "Surgery Protocol for Ebola Includes AAMI Gown Standard." In the press release, AAMI recommends that surgeons and health care professionals wear "AAMI Level 4" surgical gowns and drapes when operating on suspected or confirmed Ebola patients. On October 21, 2014, the American College of Surgeons issued a statement echoing the AAMI guidance by advising that due to the significant risk of exposure to blood or bodily fluids, all operating room personnel should wear "AAMI Level 4" impervious surgical gowns. Again, while the public and the health care community is being led to believe that "AAMI Level 4" gowns manufactured and distributed by KC are safe for Ebola patients or other sensitive operations, and KC's gowns have met critical industry standards and are "impermeable," KC together with certain of its employees, executives, agents, distributors, and others have been silent in disclosing the truth.

## V. CLASS ACTION ALLEGATIONS

**Fed. R. Civ. Proc. 23(b)(2)**

30. Plaintiff brings this action pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure on behalf of himself and all purchasers and users, including entities and natural persons, in the United States who purchased or used the KC High Performance Gowns from 2011 to the present (the "Injunctive Relief Class"), with the following subclass:

(a) All purchasers and users, including entities and natural persons in California, who purchased or used the High Performance Gowns from 2011 to the present (the "California Injunctive Relief Subclass").

31. Excluded from the Injunctive Relief Class is any governmental entity and any person or entity in which any judge, justice, or judicial officer presiding over this

matter and members of their immediate families and judicial staff, have any controlling interest. Excluded from the Injunctive Relief Class is any partner or employee of Class Counsel. Plaintiff reserves the right to modify the Class description and the Class based on the results of discovery.

32. Class certification is proper under Rule 23 of the Federal Rules of Civil Procedure because KC has acted (or refused to act) on grounds generally applicable to the Injunctive Relief Class thereby making appropriate injunctive relief with respect to the Injunctive Relief Class as a whole.

33. Plaintiff reserves the right to modify the definition of the Injunctive Relief Class after further discovery, and further reserve the right to only seek class certification under Rule 23(b)(2) for injunctive relief and not to seek class certification under Rule 23(b)(3) for monetary damages.

**Fed. R. Civ. Proc. 23(b)(3)**

34. Plaintiff separately brings this action pursuant to Rule 23(b)(3) of the Federal Rules of Civil Procedure on behalf of himself and all purchasers and users, including entities and natural persons, in the United States who purchased or used the KC High Performance Gowns from 2011 to the present (the "Damages Class"), with the following subclass:

(a) All purchasers and users, including entities and natural persons in California, who purchased or used the High Performance Gowns from 2011 to the present (the "California Damages Subclass").

35. Excluded from the Damages Class is any governmental entity and any person or entity in which any judge, justice, or judicial officer presiding over this matter and members of their immediate families and judicial staff, have any controlling interest. Excluded from the Damages Class is any partner or employee of Class Counsel. Plaintiff reserves the right to modify the class description and the class based on the results of discovery.

36. Questions of law or fact common to Damages Class members predominate over any questions affecting only individual Damages Class members, and a class action is superior to other available methods for fairly and efficiently adjudicating the controversy.

37. Plaintiffs reserve the right to modify the definition of the Damages Class after further discovery and further reserve the right to only seek class certification under Rule 23(b)(2) for injunctive relief and not to seek class certification under Rule 23(b)(3) for monetary damages.

**Fed. R. Civ. Proc. 23(a) Prerequisites**

38. The Injunctive Relief Class and Damages Class are sometimes referred to collectively herein as the "Class" and the members of the Class as "Class Members."

39. The California Injunctive Relief Class and California Damages Class are sometimes referred to collectively herein as the "California Class".

40. Numerosity of the Class. The Injunctive Relief Class is so numerous that joinder of all members in one action is impracticable. While the exact number and identities of Injunctive Relief Class Members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes and therefore alleges that there are in excess of 500,000 members of the Injunctive Relief Class. The Damages Class is so numerous that joinder of all members in one action is impracticable. While the exact number and identities of Damages Class Members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes and therefore alleges that there are in excess of 500,000 members of the Damages Class.

41. Typicality of Claims. Plaintiff's claims are typical of those of other Injunctive Relief Class Members and also of other Damages Class Members, all of whom have suffered similar harm due to KC and/or its distributors' course of conduct as described herein.

42. Adequacy of Representation. Plaintiff is an adequate representative of the Injunctive Relief Class and the Damages Class and will fairly and adequately protect the interests of both Classes and have retained attorneys who are highly experienced in the handling of class actions, and Plaintiffs and their counsel intend to prosecute this action vigorously.

43. Predominance of Common Questions of Law or Fact. Common questions of fact and law exist as to all Class Members that predominate over any questions affecting only individual Class Members. These common legal and factual questions, which do not vary among Class Members, and which may be determined without reference to the individual circumstances of any Class member, include, but are not limited to, the following:

(a) Whether KC and/or its distributors represented that the High Performance Gowns are impermeable and protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material;

(b) Whether KC and/or its distributors represented that the High Performance Gowns meet AAMI Level 4 Liquid Barrier Standards;

(c) Whether KC and/or its distributors represented that the High Performance Gowns provide "Level 4" liquid barrier protection to "critical zones," which include "the sleeves from the cuff to above the elbow";

(d) Whether and when KC and/or its distributors learned that the above representations were false;

(e) Whether KC and/or its distributors disclosed to their customers, patients the government, health care professionals, and/or the general public that the above representations were false;

(f) Whether the above representations were material;

(g) Whether KC and/or its distributors intentionally or recklessly concealed that the High Performance Gowns were not impermeable, did not meet AAMI Level 4 Liquid Barrier Standards, and did not provide "Level 4" liquid barrier protection to all "critical zones";

(h) Whether KC and/or its distributors had any reasonable grounds for believing the representations described above were true when they made them;

(i) Whether KC and/or its distributors' conduct was undertaken with conscious disregard of the rights of the members of the Class, and was done with fraud, oppression, and/or malice;

(j) Whether injunctive relief is appropriate and necessary to enjoin KC and/or its distributors from selling the High Performance Gowns;

(k) Whether KC and/or its distributors' disclosures regarding the lack of liquid barrier protection afforded by the High Performance Gowns were inadequate so as to be false, deceptive, and/or unfair;

(l) Whether KC and/or its distributors' conduct was an "unfair practice," within the meaning of California Unfair Competition Laws;

(m) Whether KC and/or its distributors' conduct was an "unlawful" practice within the meaning of the UCL;

(n) Whether KC and/or its distributors' conduct was a "fraudulent practice" within the meaning of the UCL in that it is likely to mislead consumers;

(o) Whether KC and/or its distributors engaged in untrue and/or misleading marketing and/or advertising by marketing and/or advertising the High Performance Gowns as being impermeable, meeting AAMI Level 4 Liquid Barrier Standards, and meeting other standards as represented;

(p) Whether KC and/or its distributors' conduct caused harm to the Class;

(q) Whether the members of the Class are entitled to restitution and/or suffered damages.

44. Superiority. A class action is superior to other available methods for the fair and efficient adjudication of this controversy, because individual litigation of the claims of all Class Members is impracticable. Requiring each individual class member to file an individual lawsuit would unreasonably consume the amounts that may be recovered. Even if every Class Member could afford individual litigation, the adjudication of hundreds of thousands of identical claims would be unduly burdensome to the courts. Individualized litigation would also present the potential for varying, inconsistent, or contradictory judgments and would magnify the delay and expense to all parties and to the court system resulting from multiple trials of the same factual issues. By contrast, the conduct of this action as a class action, with respect to some or all of the issues presented herein, presents no management difficulties, conserves the resources of the parties and of the court system, and protects the rights of the Class Members. Plaintiff anticipates no difficulty in the management of this action as a class action. The prosecution of separate actions by individual Class Members may create a risk of adjudications with respect to them that would, as a practical matter, be dispositive of the interests of the other Class Members not parties to such adjudications or that would substantially impair or impede the ability of such non-party Class members to protect their interests.

## VI. CLAIMS FOR RELIEF

### COUNT ONE

### FRAUD (AFFIRMATIVE MISREPRESENTATIONS)

45. Plaintiff restates and re-alleges paragraphs 1 through 44 as if fully set forth herein.

46. KC and/or its distributors uniformly represented that the High Performance Gowns:

(a) are impermeable and protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material;

(b) meet AAMI Level 4 Liquid Barrier Standards;

(c) meet ASTM F1670 and ASTM F1671 standards for resistance of materials used in protective clothing;

(d) meet ASTM F1671 standards for bacteriophage penetration, as well as the European Norms (ENISO 22610) for resistance to wet microbial penetration;

(e) provide "Level 4" liquid barrier protection to "critical zones," which include the front area of the gown from chest to knees and "the sleeves from the cuff to above the elbow";

(f) will not leak bodily fluids or pass bacterial organisms either from the health care worker to the patient, or vice versa, and are safe for use in the treatment of patients with infectious diseases or whose treatment require a sterile environment; and/or

(g) provide the highest level of liquid barrier protection such that the gowns are recommended in the treatment of suspected or confirmed Ebola patients.

47. KC's and/or its distributors' representations described above were false. KC and/or its distributors intentionally and/or recklessly misrepresented the material facts set forth above. The true facts include, among other things, that the High Performance Gowns:

(a) failed ASTM F1671 tests at rates that exceeded failure rates acceptable for satisfying AAMI Level 4 standards, and the tests revealed that liquid and bacterial matter penetrated the gowns.

(b) were not impermeable and did not protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material;

(c) did not meet AAMI Level 4 Liquid Barrier Standards;

(d) did not meet ASTM F1670 and ASTM F1671 standards for resistance of materials used in protective clothing;

(e) did not meet ASTM F1671 standards for bacteriophage penetration, as well as the European Norms (ENISO 22610) for resistance to wet microbial penetration;

(f) did not provide "Level 4" liquid barrier protection to the "critical zone" of "the sleeves from the cuff to above the elbow";

(g) did not prevent the leakage of bodily fluids or the passing of bacterial organisms between health care professionals and patients, and was not safe for use in the treatment of patients with infectious diseases or whose treatment require a sterile environment; and/or

(h) did not provide the highest level of liquid barrier protection such that the gowns are recommended in the treatment of suspected or confirmed Ebola patients

48. KC and/or its distributors' statements were made with the intent to deceive Plaintiff and the Class.

49. Plaintiff and the Class, at the time these representations were made by KC and/or its distributors, and at the time Plaintiff and the Class took the actions herein alleged, were ignorant of the falsity of KC and/or its distributors' representations and believed them to be true. Plaintiff and the Class relied on KC and/or its distributors' representations and had Plaintiff and the Class known of the actual facts, Plaintiff and the Class would not have taken the actions they did, including but not limited to purchasing the High Performance Gowns and using the High Performance Gowns in

the treatment of patients. Plaintiff and the Class' reliance on KC and/or its distributors' representations was justified.

50. As a direct and proximate result of the above, Plaintiff and the Class have suffered economic and non-economic damages in an amount to be proven at trial.

51. KC undertook the aforesaid illegal acts intentionally or with conscious disregard of the rights of Plaintiff and the Class, and did so with fraud, oppression, and/or malice. This despicable conduct subjected Plaintiff and the Class to cruel and unjust hardship so as to justify an award of punitive damages in an amount sufficient to deter such wrongful conduct in the future. Therefore, Plaintiff and the Class are also entitled to punitive damages against KC in an amount to be determined at trial.

## COUNT TWO

## FRAUDULENT CONCEALMENT/NON-DISCLOSURE

52. Plaintiff restates and re-alleges paragraphs 1 through 51 as if fully set forth herein

53. As alleged above, KC and/or its distributors made a number of representations concerning the High Performance Gowns, including that the High Performance Gowns are impermeable, meet AAMI Level 4 Liquid Barrier Standards, meet ASTM F1670 and ASTM F1671 standards, and provide "Level 4" liquid barrier protection to "critical zones," which include "the sleeves from the cuff to above the elbow."

54. KC and/or its distributors' representations described above were false. However, despite knowing of the falsity of their representations at least as of 2013, KC and/or its distributors concealed, and/or failed to disclose material and contrary facts set forth above, including, among other things, that the High Performance Gowns:

(a) failed ASTM F1671 tests at rates that exceeded failure rates acceptable for satisfying AAMI Level 4 standards, and the tests revealed that liquid and bacterial matter penetrated the gowns.

(b) were not impermeable and did not protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material;

(c) did not meet AAMI Level 4 Liquid Barrier Standards;

(d) did not meet ASTM F1670 and ASTM F1671 standards for resistance of materials used in protective clothing;

(e) did not meet ASTM F1671 standards for bacteriophage penetration, as well as the European Norms (ENISO 22610) for resistance to wet microbial penetration;

(f) did not provide "Level 4" liquid barrier protection to the "critical zone" of "the sleeves from the cuff to above the elbow";

(g) did not prevent the leakage of bodily fluids or the passing of bacterial organisms between health care professionals and patients, and was not safe for use in the treatment of patients with infectious diseases or whose treatment require a sterile environment; and/or

(h) did not provide the highest level of liquid barrier protection such that the gowns are recommended in the treatment of suspected or confirmed Ebola patients

55. KC and/or its distributors concealed and failed to disclose these material facts with the intent to deceive Plaintiff and the Class.

56. KC and/or its distributors' concealments and non-disclosure of material facts as set forth above were made with the intent to induce Plaintiff and the Class to act in the manner herein alleged in reliance thereon.

57. Plaintiff and the Class, at the time these failures to disclose and suppressions of facts occurred, and at the time Plaintiff and the Class took the actions herein alleged, were ignorant of the existence of the facts that KC and/or its distributors suppressed and failed to disclose. If Plaintiff and the Class had known of KC and/or its distributors' concealments and failures to disclose material facts, they would not have

taken the actions they did, including but not limited to purchasing the High Performance Gowns and using the High Performance Gowns in the treatment of patients. Plaintiff and the Class' reliance was justified and reasonable as they had no basis to doubt the original representations made to them, nor did they have reason to believe they were being misled or material facts were being concealed from them.

58. As a direct and proximate result of the above, Plaintiff and the Class have suffered economic and non-economic damages in an amount to be proven at trial.

59. KC undertook the aforesaid illegal acts intentionally or with conscious disregard of the rights of Plaintiff and the Class, and did so with fraud, oppression, and/or malice. This despicable conduct subjected Plaintiff and the Class to cruel and unjust hardship so as to justify an award of punitive damages in an amount sufficient to deter such wrongful conduct in the future. Therefore, Plaintiff and the Class are also entitled to punitive damages against KC in an amount to be determined at trial.

## COUNT THREE

## NEGLIGENT MISREPRESENTATION

60. Plaintiff restates and re-alleges paragraphs 1 through 59 as if fully set forth herein.

61. KC and/or its distributors uniformly represented that the High Performance Gowns:

(a) are impermeable and protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material;

(b) meet AAMI Level 4 Liquid Barrier Standards;

(c) meet ASTM F1670 and ASTM F1671 standards for resistance of materials used in protective clothing;

(d) meet ASTM F1671 standards for bacteriophage penetration, as well as the European Norms (ENISO 22610) for resistance to wet microbial penetration;

(e) provide "Level 4" liquid barrier protection to "critical zones," which include the front area of the gown from chest to knees and "the sleeves from the cuff to above the elbow";

(f) will not leak bodily fluids or pass bacterial organisms either from the health care worker to the patient, or vice versa, and are safe for use in the treatment of patients with infectious diseases or whose treatment require a sterile environment; and/or

(g) provide the highest level of liquid barrier protection such that the gowns are recommended in the treatment of suspected or confirmed Ebola patients.

62. KC's and/or its distributors' representations described above were false. The true facts include, among other things, that the High Performance Gowns:

(a) failed ASTM F1671 tests at rates that exceeded failure rates acceptable for satisfying AAMI Level 4 standards, and the tests revealed that liquid and bacterial matter penetrated the gowns.

(b) were not impermeable and did not protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material;

(c) did not meet AAMI Level 4 Liquid Barrier Standards;

(d) did not meet ASTM F1670 and ASTM F1671 standards for resistance of materials used in protective clothing;

(e) did not meet ASTM F1671 standards for bacteriophage penetration, as well as the European Norms (ENISO 22610) for resistance to wet microbial penetration;

(f) did not provide "Level 4" liquid barrier protection to the "critical zone" of "the sleeves from the cuff to above the elbow";

(g) did not prevent the leakage of bodily fluids or the passing of bacterial organisms between health care professionals and patients, and was not safe for use in the treatment of patients with infectious diseases or whose treatment require a sterile environment; and/or

(h) did not provide the highest level of liquid barrier protection such that the gowns are recommended in the treatment of suspected or confirmed Ebola patients

63. KC and/or its distributors had no reasonable grounds for believing the representations described above were true when they made them.

64. KC and/or its distributors intended that Plaintiff and the Class rely on these representations.

65. Plaintiff and the Class, at the time these representations were made by KC and/or its distributors, and at the time Plaintiff and the Class took the actions herein alleged, were ignorant of the falsity of KC and/or its distributors' representations and believed them to be true. Plaintiff and the Class relied on KC and/or its distributors' representations and had Plaintiff and the Class known of the actual facts, Plaintiff and the Class would not have taken the actions they did, including but not limited to purchasing the High Performance Gowns and/or using the High Performance Gowns in the treatment of patients. Plaintiff and the Class' reliance on KC and/or its distributors' representations was justified.

66. As a direct and proximate result of the above, Plaintiff and the Class have suffered economic and non-economic damages in an amount to be proven at trial.

67. KC undertook the aforesaid illegal acts intentionally or with conscious disregard of the rights of Plaintiff and the Class, and did so with fraud, oppression, and/or malice. This despicable conduct subjected Plaintiff and the Class to cruel and unjust hardship so as to justify an award of punitive damages in an amount sufficient to

deter such wrongful conduct in the future. Therefore, Plaintiff and the Class are also entitled to punitive damages against KC in an amount to be determined at trial.

## COUNT FOUR

## VIOLATION OF CALIFORNIA BUSINESS AND PROFESSIONS CODE SECTION 17200 *ET SEQ.*

68. Plaintiff restates and re-alleges paragraphs 1 through 67 as if fully set forth herein.

69. California Business and Professions Code section 17200 *et seq.*, also known as the California Unfair Competition Law ("UCL"), prohibits acts of "unfair competition," including any unlawful, unfair, fraudulent, or deceptive business act or practice as well as "unfair, deceptive, untrue or misleading advertising."

70. By engaging in the false, deceptive, and misleading conduct alleged above, KC and/or its distributors have engaged in unlawful business acts and practices in violation of the UCL, including by violating state and federal laws, including but not limited to 21 U.S.C. § 360; and 21 C.F.R. §§ 803.1 *et seq.*, 21 C.F.R. § 878.4040, and Cal. Bus. & Prof. Code §§ 17500 *et seq.*

71. KC and/or its distributors' conduct in misleading Plaintiff and the Class through its affirmative misrepresentations and failures to disclose material facts to Plaintiff and the Class, as described above, also constitutes a "fraudulent" and "unfair" business practice within the meaning of the UCL.

72. Plaintiff and each Class Member suffered an injury in fact and lost money or property as a result of KC and/or its distributors' unlawful, unfair, and/or fraudulent business practices.

73. Plaintiff, on behalf of himself and the Class, seeks restitution and disgorgement of all moneys received by KC and/or its distributors through the unlawful and fraudulent conduct described above.

74. Plaintiff, on behalf of himself and the Class, seeks a temporary, preliminary, and/or permanent injunction from this Court prohibiting KC and/or its distributors from engaging in the patterns and practices described herein.

## COUNT FIVE

## VIOLATION OF CALIFORNIA BUSINESS AND PROFESSIONS CODE SECTION 17500 *ET SEQ.*

75. Plaintiff restates and re-alleges paragraphs 1 through74 as if fully set forth herein.

76. California Business and Professions Code section 17500 et seq., also known as the California False Advertising Law, makes it "unlawful for any person, . . . corporation or association, or any employee thereof with intent directly or indirectly to dispose of . . . personal property . . . or anything of any nature whatsoever . . . to make or disseminate or cause to be made or disseminated from this state before the public in any state, in any newspaper or other publication, or any advertising device, or by public outcry or proclamation, or in any other manner or means whatsoever, including over the Internet, any statement, concerning that . . . personal property . . . or concerning any circumstance or matter of fact connected with the proposed performance or disposition thereof, which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading . . ." Cal. Bus. & Prof. Code § 17500.

77. As alleged above, KC and/or its distributors disseminated or caused to be disseminated to the general public through various media deceptive advertising regarding the High Performance Gowns. More specifically, as a solicitation to Plaintiff and the Class to patronize the products provided by KC and/or its distributors, and as a material part thereof, KC and/or its distributors made various representations to Plaintiff and the Class concerning the High Performance Gowns that were untrue or misleading, including, among other things, that the High Performance Gowns:

(a) are impermeable and protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material;

(b) meet AAMI Level 4 Liquid Barrier Standards;

(c) meet ASTM F1670 and ASTM F1671 standards for resistance of materials used in protective clothing;

(d) meet ASTM F1671 standards for bacteriophage penetration, as well as the European Norms (ENISO 22610) for resistance to wet microbial penetration;

(e) provide "Level 4" liquid barrier protection to "critical zones," which include the front area of the gown from chest to knees and "the sleeves from the cuff to above the elbow";

(f) will not leak bodily fluids or pass bacterial organisms either from the health care worker to the patient, or vice versa, and are safe for use in the treatment of patients with infectious diseases or whose treatment require a sterile environment; and/or

(g) provide the highest level of liquid barrier protection such that the gowns are recommended in the treatment of suspected or confirmed Ebola patients.

78. KC and/or its distributors continue to disseminate or cause to be disseminated such untrue and/or misleading representations concerning the High Performance Gowns as alleged above. Indeed, despite knowing the falsity of their claims at least as of 2013 when KC learned about the failed test results for the High Performance Gowns, KC and/or its distributors failed to disclose the true facts concerning the High Performance Gowns as alleged above.

79. The untrue and/or misleading statements KC and/or distributors caused to be disseminated concerning the High Performance Gowns as alleged above have deceived Plaintiff and the Class and are likely to deceive the consuming public.

80. While disseminating or causing to be disseminated the untrue and/or misleading statements concerning the High Performance Gowns as alleged above, KC and/or its distributors knew or should have known that the representations were false, deceptive, and/or misleading.

81. As a direct and proximate result of KC and/or its distributors' untrue and/or misleading representations concerning the High Performance Gowns as alleged above, KC and/or its distributors knew or should have known that the representations were untrue and/or misleading.

82. As a direct and proximate result of KC and/or its distributors' untrue and/or misleading representations concerning the High Performance Gowns as alleged above, Plaintiff and the members of the Class have been injured in fact, in that they purchased and/or used the High Performance Gowns in reliance on KC and/or its distributors' untrue and/or misleading representations and would not have purchased had the truth been adequately disclosed.

83. KC and/or its distributors' untrue and/or misleading representations as alleged above presents a continuing threat to Plaintiff, the Class, and members of the public because KC and/or its distributors continue to disseminate untrue and/or misleading advertising, and will not cease doing so unless and until enjoined or restrained by this Court.

84. Under California Business and Professions Code section 17535, Plaintiff, on behalf of himself, the Class Members, and members of the general public, seek an order of this Court:

(a) For injunctive relief requiring KC and/or its distributors to disclose, on its website and on the packaging of all the High Performance Gowns, that the High Performance Gowns are <u>not</u> impermeable, do <u>not</u> protect both the surgical patient and operating room personnel from transfer of microorganisms, body fluids, and particulate matter,

do not meet AAMI Level 4 Liquid Barrier Standards, and do not meet ASTM F1670 and F1671 standards; and

(b) Restitution of all monies paid to KC and/or its distributors for the High Performance Gowns.

## VII. PRAYER FOR RELIEF

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

**ON THE FIRST CAUSE OF ACTION FOR FRAUD (AFFIRMATIVE MISREPRESENTATIONS)**

1. An Order certifying that the action be maintained as a class action under Rule 23(b)(2) and/or Rule 23(b)(3) of the Federal Rules of Civil Procedure.

2. An injunction precluding the wrongful conduct described herein.

3. For compensatory damages in an amount that exceeds $500 million, with the exact amount to be proven at trial.

4. For punitive damages in an amount sufficient to punish Defendants and to defer them from engaging in wrongful conduct in the future.

5. For pre and post judgment interest and costs of suit incurred herein.

6. For attorneys' fees incurred herein, to the extent permitted by law.

7. For such other and further relief as the Court may deem just and proper.

**ON THE SECOND CAUSE OF ACTION FOR FRAUDULENT CONCEALMENT**

1. An Order certifying that the action be maintained as a class action under Rule 23(b)(2) and/or Rule 23(b)(3) of the Federal Rules of Civil Procedure.

2. An injunction precluding the wrongful conduct described herein.

3. For compensatory damages in an amount that exceeds $500 million, with the exact amount to be proven at trial.

4. For punitive damages in an amount sufficient to punish Defendants and to defer them from engaging in wrongful conduct in the future.

5. For pre and post judgment interest and costs of suit incurred herein.

6. For attorneys' fees incurred herein, to the extent permitted by law.

7. For such other and further relief as the Court may deem just and proper.

**ON THE THIRD CAUSE OF ACTION FOR NEGLIGENT MISREPRESENTATION**

1. An Order certifying that the action be maintained as a class action under Rule 23(b)(2) and/or Rule 23(b)(3) of the Federal Rules of Civil Procedure.

2. An injunction precluding the wrongful conduct described herein.

3. For compensatory damages in an amount that exceeds $500 million, with the exact amount to be proven at trial.

4. For pre and post judgment interest and costs of suit incurred herein.

5. For attorneys' fees incurred herein, to the extent permitted by law.

6. For such other and further relief as the Court may deem just and proper.

**ON THE FOURTH CAUSE OF ACTION FOR VIOLATIONS OF THE UNFAIR COMPETITION LAW (CAL. BUS. & PROF. CODE §§ 17200 *ET SEQ.*)**

1. An Order certifying that the action be maintained as a class action under Rule 23(b)(2) and/or Rule 23(b)(3) of the Federal Rules of Civil Procedure.

2. An injunction precluding the wrongful conduct described herein.

3. For restitution of moneys paid for property in an amount that exceeds $500 million, with the exact amount to be proven at trial.

4. An award of equitable and declaratory relief.

5. For pre and post judgment interest and costs of suit incurred herein.

6. For attorneys' fees incurred herein, to the extent permitted by law.

7. For such other and further relief as the Court may deem just and proper.

**ON THE FIFTH CAUSE OF ACTION FOR FALSE ADVERTISING (CAL. BUS. & PROF. CODE §§ 17500 *ET SEQ.*)**

1. An Order certifying that the action be maintained as a class action under Rule 23(b)(2) and/or Rule 23(b)(3) of the Federal Rules of Civil Procedure.

2. An injunction precluding the wrongful conduct described herein and requiring KC and/or its distributors to disclose, on its website and on the packaging of all the High Performance Gowns, that the High Performance Gowns are not impermeable, do not protect both the surgical patient and operating room personnel from transfer of microorganisms, body fluids, and particulate matter, do not meet AAMI Level 4 Liquid Barrier Standards, and do not meet ASTM F1670 and F1671 standards.

3. For restitution of moneys paid for property in an amount that exceeds $500 million, with the exact amount to be proven at trial.

4. An award of equitable and declaratory relief.

5. For pre and post judgment interest and costs of suit incurred herein.

6. For attorneys' fees incurred herein, to the extent permitted by law.

7. For such other and further relief as the Court may deem just and proper.

Dated: October 29, 2014

EAGAN AVENATTI, LLP

By: _____
Michael J. Avenatti
Attorneys for Plaintiffs

**JURY DEMAND**

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

Dated: October 29, 2014

EAGAN AVENATTI, LLP

By: _____
Michael J. Avenatti
Attorneys for Plaintiffs

# Exhibit A

# MicroCool Surgical Gown Meets AAMI Level 4 Requirements


http://www.infectioncontroltoday.com/
By:
Posted on: 05/16/2011

PRINT

Kimberly-Clark Health Care announces that it has been cleared by the Food and Drug Administration (FDA) to market its MicroCool* Breathable High Performance Surgical Gown as meeting the Association for the Advancement of Medical Instrumentation (AAMI) Level 4 Standard for liquid barrier protection. The AAMI Standard is a system of liquid barrier performance classification for protective apparel. The gown, featuring the updated labeling, is expected to be available in select locations beginning this month and to the complete market by the end of this year.

The AAMI Standard addresses four levels of barrier protection – ranging from Level 1 to Level 4. Gowns with a Level 4 classification provide the highest liquid barrier protection defined by the AAMI Standard. The classification of the entire surgical gown under the AAMI Standard is based on the lowest level of protection within any of its Critical Zones.

Kimberly-Clark Health Care, utilizing feedback from its customers, developed the new MicroCool* Breathable High Performance Surgical Gown, with the highest AAMI level of liquid barrier protection while still providing the same comfort and critical lint, abrasion, flame and bacteria resistance that its customers need.

The single-use gown helps prevent blood and other bodily fluids from penetrating through to the clinician's skin during any procedure and is specifically designed for the most demanding and fluid-intensive procedures. Incorporating adhesive laminate technology, the gown features an advanced microporous fabric, which utilizes two layers of nonwoven fabric to enclose a protective film layer that "breathes," dispelling body heat to keep the wearer cool and comfortable.

This level of innovation further illustrates Kimberly-Clark Health Care's commitment to designing products that meet customer needs.

"As a pioneer in the development of MicroCool* technology, Kimberly-Clark Health Care has a long heritage of providing the most innovative products to our customers," says John Amat, vice president of global sales and marketing, Kimberly-Clark Health Care. "The gown delivers surgeons and surgical staff a full spectrum of protection and the assurance of barrier integrity, allowing them to concentrate solely on patient care during long and stressful procedures and not on their risk of exposure," said Amat.

Consistent with Kimberly-Clark Health Care's commitment to sustainability and providing a "greener" healthcare community, the MicroCool* Breathable High Performance Surgical Gown's, AAMI Level 4 barrier performance fabric technology is PFOA-free and adheres to the Environmental Protection Agency's (EPA) standard for protecting the environment.

"We create our own fabrics in house. This vertical-integration system allows us to drastically reduce both our impact on the environment and our customers' pockets," Amat adds.



EXHIBIT A

# Exhibit B

Kimberly-Clark

Home ❯ MICROCOOL* Breathable High Performance Surgical Gown

Surgical Solutions

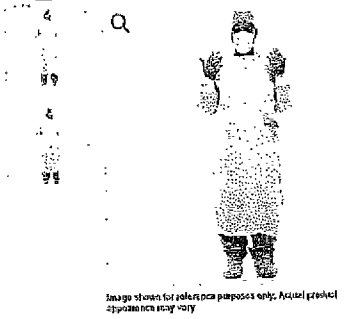

Image shown for reference purposes only. Actual product appearance may vary

## MICROCOOL* Breathable High Performance Surgical Gown

- MICROCOOL* Gown meets both the AAMI Level 4 Liquid Barrier Standard and ASTM F1670 and ASTM F1671 standards for resistance of materials used in protective clothing [1,2]
- Meets the ASTM F1671 standard for bacteriophage penetration, as well as the European Norms (EN/ISO 22610) for resistance to wet microbial penetration [2,3]
- Meets the ISO standard for ignition resistance (ISO 11810-1 Class I1-21—No Ignition) [2]
- Meets ASTM D4966 for abrasion resistance and produces fewer than 20 particles of lint at the 10-micron level on the Gelbo lint test [5]
- MICROCOOL* fabric allows moisture vapor to pass through almost instantly, compared to competitive gown materials, as measured by the Moisture Vapor Transfer test [4]
- Raglan sleeves
- Adjustable neckline
- Specialty options for seated procedures
- Generous cut
- Sterile and non-sterile options available

[1] Meets AAMI level 4 Liquid Barrier Standard and ANSI/AAMI PB70: 2003 Liquid barrier performance and classification of protective apparel and drapes intended for use in healthcare facilities.

[2] Per Kimberly-Clark product specifications

[3] MICROCOOL* Surgical gowns pass ASTM 1671 Standard Test Method for resistance of materials used in protective clothing to penetration of bloodborne pathogens using

[4] Data on file, Kimberly-Clark Health Care

# Description

### MICROCOOL* Breathable High Performance Surgical Gown

The new MICROCOOL* Breathable High Performance Surgical Gown is the result of years of research to make MICROCOOL* more cool and protective than ever. Kimberly-Clark has a long heritage of medical fabric leadership, with over 650 US and international patents for advanced non-woven fabrics.

**Patented Microporous Fabric**

- Soft spunbound outer layer
- Proprietary breathable fabric
- SMS fabric inner liner layer

### MICROCOOL* Gowns meet the AAMI Level 4 liquid barrier standard [1]

The Association for the Advancement of Medical Instrumentation (AAMI) developed the liquid barrier standard to assist healthcare personnel in the selection and use of surgical gowns, drapes and other protective apparel. MICROCOOL* Gowns are Level 4, the highest barrier protection rating available for gowns. KIMBERLY-CLARK* MICROCOOL* Breathable High Performance Surgical Gowns provide Level 4 liquid barrier in zones A, B, and C.[2,3] For surgical gowns, the critical zones are, at a minimum, the front area of the gown from chest to knees (area A) and the sleeves from the cuff to above the elbow (area B). The standard requires that the entire front of a surgical gown (Areas A, B, and C) provide a liquid barrier of at least Level 1. The back of the gown (area D) may be non-protective.

**100% Landfill free**



EXHIBIT B

MICROCOOL* Gowns are produced in facilities dedicated to cleaner manufacturing and source reduction. Every month, over 6.5 million pounds of our manufacturing waste is diverted from landfills. And the facility which manufactures our MICROCOOL* fabric is 100% landfill-free.

### Clean Incineration

MICROCOOL* Gowns are composed of over 90% Number 5 polypropylene, which incinerates very cleanly after use.[4] (Compare that to reusable gowns, which require substantial amounts of water, energy, and harsh chemicals to decontaminate and clean according to industry standards for hospital laundry.[5])

### PFOA-free

In compliance with EPA recommendations, MICROCOOL* Gowns are PFOA-free.[6]

### Environmental Leadership

Our sustainability standards have helped Kimberly-Clark to be repeatedly recognized for environmental leadership by the Dow Jones Sustainability Index and the Newsweek Green Rankings of the world's most environmentally-friendly companies.

[1] Meets AAMI level 4 Liquid Barrier Standard and ANSI/AAMI PB70: 2003 Liquid barrier performance and classification of protective apparel and drapes intended for use in healthcare facilities.
[2][3] Integrated Paper Services (IPS) Test Reports: 26794, Dec 3, 2010, and 24232 Sept 1, 2010.
[2][4] Data on file, Kimberly-Clark Health Care.
[5] "A White Paper on Performance, Cost Per Use, and Environmental Impact of Single- Use and Reusable Surgical Gowns & Drapes" McIlvaine Company, 2009.
[7][8] PFOA: Perfluorooctanoic acid; EPA recommendations to eliminate PFOA chemistry utilization. "PFOA-free" means that a product has PFOA below 20 ppb as manufactured. (Source: www.epa.gov/oppt/pfoa/pubs/stewardship/ )

## Specifications

| | |
|---|---|
| Brand | MICROCOOL* |
| UNSPSC Code | 42131702 |
| Fabric | SFSMS |
| Name | MICROCOOL* Breathable High Performance Surgical Gown |
| Cut of Gown | Generous Cut |
| Procedure | Standing Procedures |
| Fold | Book |
| Low Lint | Yes |
| Neck Binding Color | Red |
| Sleeve Type | Raglan Sleeves |
| Specialty Gown | No |
| Abrasion Resistance | Meets ASTM D4966 |
| Expected Fluid Contact | High; For Lengthy, Fluid-Intensive Procedures |
| Flame Resistance | Meets NFPA Class I and ISO 11810 |
| AAMI Protection Level | AAMI Level 4 Liquid Barrier Protection |
| Closure | Hook-and-Loop |

## Selected Filters

| Size | Gown Length | Sterile | Packaging |
|---|---|---|---|
| Large | Extra Long | Yes | Handi-Bin |
| X-Large | Standard | No | N/A |
| XX-Large | | | |

## 12 Products Available

**79729**
Large Regular Non-Sterile Handi-Bin

| | | | |
|---|---|---|---|
| Size: | Large | Units per Case: | 528 |
| Includes Towel: | No | | |
| Gown Length: | Standard | | |
| Sterile: | No | | |
| Packaging: | Handi-Bin | See Packaging Specifications | » |

**79739**
X-Large Regular Non-Sterile Handi-Bin

| | | | |
|---|---|---|---|
| Size: | X-Large | Units per Case: | 432 |
| Includes Towel: | No | | |
| Gown Length: | Standard | | |
| Sterile: | No | | |
| Packaging: | Handi-Bin | See Packaging Specifications | » |

**72438**
Large Regular Non-Sterile

| | | | |
|---|---|---|---|
| Size: | Large | Units per Case: | 40 |
| Includes Towel: | No | | |
| Gown Length: | Standard | | |
| Sterile: | No | | |
| Packaging: | N/A | See Packaging Specifications | » |

**72445**
X-Large Regular Non-Sterile

| | | | |
|---|---|---|---|
| Size: | X-Large | Units per Case: | 32 |
| Includes Towel: | No | | |
| Gown Length: | Standard | | |
| Sterile: | No | | |
| Packaging: | N/A | See Packaging Specifications | » |

**72447**
XX-Large Regular Non-Sterile

| | | | |
|---|---|---|---|
| Size: | XX-Large | Units per Case: | 32 |
| Includes Towel: | No | | |
| Gown Length: | Standard | | |
| Sterile: | No | | |
| Packaging: | N/A | See Packaging Specifications | » |

**73038**
Large X-Long Non-Sterile

| | | | |
|---|---|---|---|
| Size: | Large | Units per Case: | 36 |
| Includes Towel: | No | | |
| Gown Length: | Extra Long | | |
| Sterile: | No | | |
| Packaging: | N/A | See Packaging Specifications | » |

**73041**
X-Large X-Long Non-Sterile

| | | | |
|---|---|---|---|
| Size: | X-Large | Units per Case: | 32 |
| Includes Towel: | No | | |
| Gown Length: | Extra Long | | |
| Sterile: | No | | |
| Packaging: | N/A | See Packaging Specifications | » |

**92038**
Large Includes Towel X-Long Sterile

| | | | |
|---|---|---|---|
| Size: | Large | Units per Case: | 30 |
| Includes Towel: | Yes | | |
| Gown Length: | Extra Long | | |
| Sterile: | Yes | | |
| Packaging: | N/A | See Packaging Specifications | » |

**92042**
X-Large Includes Towel X-Long Sterile

| | | | |
|---|---|---|---|
| Size: | X-Large | Units per Case: | 30 |
| Includes Towel: | Yes | | |
| Gown Length: | Extra Long | | |
| Sterile: | Yes | | |
| Packaging: | N/A | See Packaging Specifications | » |

**92340**
Large Includes Towel Regular Sterile

| | | | |
|---|---|---|---|
| Size: | Large | Units per Case: | 30 |
| Includes Towel: | Yes | | |
| Gown Length: | Standard | | |
| Sterile: | Yes | | |
| Packaging: | N/A | See Packaging Specifications | » |

**92342**
X-Large Includes Towel Regular Sterile

| | | | |
|---|---|---|---|
| Size: | X-Large | Units per Case: | 28 |
| Includes Towel: | Yes | | |
| Gown Length: | Standard | | |
| Sterile: | Yes | | |
| Packaging: | N/A | See Packaging Specifications | » |

**92344**
XX-Large Includes Towel Regular Sterile

| | | | |
|---|---|---|---|
| Size: | XX-Large | Units per Case: | 26 |
| Includes Towel: | Yes | | |
| Gown Length: | Standard | | |
| Sterile: | Yes | | |
| Packaging: | N/A | See Packaging Specifications | » |

# Exhibit C

Kimberly-Clark Healt ×

www.kchealthcare.com/about-us/news/2014/august/kimberly-clark-pandemic-preparedness-customer-letter.aspx

Kimberly-Clark

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08/15/2014

Kimberly-Clark Pandemic Preparedness Customer Letter

As concerns around the spread of the Ebola virus continue to grow, the number of inquiries we receive at Kimberly-Clark regarding recommendations for PPE and our plans for Pandemic Preparedness are growing in tandem. Therefore, we want to proactively provide you with guidance on preparing for a pandemic as well as solutions for proper PPE. We are providing you with a clinical Kimberly-Clark Ebola Virus Precautions Brief and a Kimberly-Clark Personal Protection Solutions guide.

Click here to download the Kimberly-Clark Pandemic Preparedness Customer Letter

Click here to download the Kimberly-Clark Ebola Virus Disease (EVD) Precautions Brief

Click here to download the Kimberly-Clark Personal Protection Solutions Guide

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EXHIBIT C

# Exhibit D

Kimberly-Clark | COMING SOON... HALYARD

August 14, 2014

Dear Valued Kimberly-Clark Customer:

In North America, as we prepare to enter the flu season, news of the spread of the Ebola virus in West Africa reminds us about the importance of following good personal protection practices while treating patients with potentially communicable infections. Kimberly-Clark joins the world in the hope for the cessation of the spread of the virus and the discovery of a cure. While the transmission of the virus in West Africa has captured the attention of the world and increased anxiety about its potential to spread into North America, we want you to rest assured that Kimberly-Clark has activated its Pandemic Preparedness Plan which provides protocols for tracking the cadence of orders and monitoring supply of our critical Personal Protection Equipment products (PPE) including facial protection, exam gloves and protective apparel.

Kimberly-Clark Health Care has deployed our North American based manufacturing assets for Facial Protection to meet any increase in demand while monitoring the situation and its effects on supply chain. Our manufacturing locations in North America make us uniquely positioned to respond quickly to increased demand for facial protection. As a part of our Pandemic Preparedness Plan, it is a primary goal to always support existing customers to meet their immediate needs for Facial Protection.

Today orders for Facial Protection continue to be filled normally. As a reminder, should the demand for Facial Protection dramatically increase, we will prioritize demand that is above normal levels as follows:

1. Protection of "First-line Responders" – Medical personnel treating the sick; primarily hospitals.
2. Protection of Pharmaceutical Production – Medication production and vaccine research
3. Protection of Global Commerce/ Transportation – Global and local transportation, shipping and airline traffic
4. Protection of Public Transportation Employees
5. Protection of Major Infrastructure (Utilities, Critical Manufacturing Customers)
6. Protection of General Public

We will continue to provide updates as information becomes available.

As a leader in Infection Prevention, Kimberly-Clark is often sought out for recommendations on Infection prevention protocol in times when there is a potential pandemic. Since the onset of Ebola, we have received numerous inquiries to that end. Therefore, we are providing you with our initial guidance regarding the Ebola virus in the ***Kimberly-Clark Ebola Virus Disease (EVD) Precautions Brief: Update August 12, 2014***.The following is an excerpt:

***TRANSMISSION***

Person-to-person transmission occurs by very close personal contact with an infected individual or with their body fluids during the late stages of infection or after their death[3,4]. During the care of an infected individual, spread of the virus can occur through contact with infected body fluids on the patient, on their clothes or bedding, on surfaces such as bedrails, side tables, the floor, or on reused unsterilized syringes, needles, thermometers or other virus-contaminated medical equipment. Humans may also be



EXHIBIT D

infected by handling sick or dead non-human primates and are also at risk when handling the bodies of deceased humans in preparation for funerals[5,6].

***Survival outside the body:*** *The virus can survive and remain infective in liquid or dried material at room temperature for a number of days[1] or at 39°F (4°C) for several days, and is indefinitely stable at -70°C. Infectivity can be preserved by lyophilization (freeze-drying)[5,25].*

See attached ***Kimberly-Clark Ebola Virus Disease (EVD) Precautions Brief: Update August 12, 2014*** for the complete Precautions Brief. For a list of PPE products available from Kimberly-Clark Health Care, please click **here**.

While Kimberly-Clark Corporation has long-standing relationships with American Red Cross Annual Disaster Giving Program and the United Way, Kimberly-Clark Health Care has also partnered with MedShare to facilitate our donation of PPE to West Africa to aid in the containment of the Ebola virus. If you would like information on how you too can contribute to these organizations, please visit their websites at:

MedShare: http://www.medshare.org/

American Red Cross Annual Disaster Giving Program: http://www.redcross.org.

United Way: http://www.unitedway.org/

If you have any additional questions, please reach out to your Kimberly-Clark Sales Representative or contact Customer Care at: 1 (800) 742-1996.

Sincerely,

Alex Hodges
General Manager, North America
Surgical & Infection Prevention

**REFERENCES**

[3] Plague In RG. Darling, & JB. Woods (Eds.), USAMRIID's Medical Management of Biological Casualties Handbook 5th ed. 2004; pp. 40-44. Fort Detrick M.D.: USAMRIID.
[4] Acha PN, Szyfres B. In Pan American Health Organization Zoonoses and Communicable Diseases Common to Man and Animals. 3rd ed. 2003; pp. 142-145. Washington D.C.: Pan American Health Organization.
[5] Mwanatambwe M, Yamada N, Arai S, et al. Ebola hemorrhagic fever (EHF): mechanism of transmission and pathogenicity. Journal of Nippon Medical School = Nihon Ika Daigaku Zasshi, 2001;68(5): 370-375.
[6] Hewlett BS. Amolat RP. Cultural contexts of Ebola in Northern Uganda. Emerg Infect Dis.2003;9(10):1242-1248.
[25] Evans, AS, & Kaslow RA. (Eds.). Viral Infections of Humans - Epidemiology and Control (4th ed.). 1997; New York, NY: Plenum Publishing Corporation.

# Exhibit E

PPE Solutions

KIMBERLY-CLARK*
Personal Protective Equipment

# *Healthcare Worker Fluid Resistant Protection*

Kimberly-Clark offers a full range of PPE solutions for healthcare facilities.

| *NIOSH Certified N95 Respirators – Pass ASTM F1862 at 160 mm Hg / High Fluid Exposure* | *Eaches/Case* |
|---|---|
| 46727 FLUIDSHIELD* N95 Particulate Filter Respirator and Surgical Mask, Regular | 210 |
| 46827 FLUIDSHIELD* N95 Particulate Filter Respirator and Surgical Mask, Small | 210 |
| 46767 FLUIDSHIELD* N95 Particulate Filter Respirator and Surgical Mask, Safety Seal, Regular | 210 |
| 46867 FLUIDSHIELD* N95 Particulate Filter Respirator and Surgical Mask, Safety Seal, Small | 210 |

| *Fluid-Resistant Face Masks – ASTM Level 3 / Pass ASTM F1862 at 160 mm Hg - High Fluid Exposure* | *Eaches/Case* |
|---|---|
| 48247 KC300 FLUIDSHIELD* Fog-Free Surgical Mask with WrapAround Anti-Glare Visor, ties | 100 |
| 48207 KC300 FLUIDSHIELD* Fog-Free Surgical Mask, ties | 300 |
| 47147 KC300 FLUIDSHIELD* Fog-Free Procedure Mask with WrapAround Visor, earloops | 100 |
| 47107 KC300 FLUIDSHIELD* Fog-Free Procedure Mask, earloops | 400 |

| *Fluid-Resistant Face Masks – ASTM Level 2 / Pass ASTM F1862 at 120 mm Hg - Moderate Fluid Exposure* | *Eaches/Case* |
|---|---|
| 62113 THE PROTECTOR* Fog-Free Surgical Mask, ties | 300 |
| 62114 THE PROTECTOR* Fog-Free Surgical Mask, with WrapAround Visor, ties | 100 |
| 62115 THE PROTECTOR* Procedure Mask, earloops | 500 |
| 62116 THE PROTECTOR* Fog-Free Procedure Mask, with WrapAround Visor, earloops | 100 |

| *Disposable Eye and Face Protection* | *Eaches/Case* |
|---|---|
| 41204 GUARDALL* Shield Face Shield, Fog-Resistant, full length | 40 |

| *KIMBERLY-CLARK PROFESSIONAL* Reusable Eye Protection* | *Eaches/Case* |
|---|---|
| 16362 JACKSON SAFETY* V80 SG34 Goggles | 50 |
| 16668 JACKSON SAFETY* V80 MONOGOGGLE* 211 Goggles | 36 |
| 16361 JACKSON SAFETY* V80 MONOGOGGLE* VPC Goggles | 36 |
| 16679 JACKSON SAFETY* V80 MRXV* Goggles | 36 |
| 18624 JACKSON SAFETY* V80 MONOGOGGLE* XTR* OTG Goggles | 6 |
| 14399 JACKSON SAFETY* V80 REVOLUTION* OTG Goggles | 30 |

| *Headwear – Light Fluid Contact* | *Eaches/Case* |
|---|---|
| 69083 SMS Bouffant Cap, White, Large 24" | 300 |
| 69086 SMS Bouffant Cap, White, X-Large 27" | 300 |
| 69110 Protective Surgical Hood with tie neck, Blue, Universal | 3 |



EXHIBIT E

| PURPLE NITRILE* Exam Gloves / Durable protection for procedures where risk of fluid exposure is moderate to high | Eaches/Case |
|---|---|
| 55090 PURPLE NITRILE* Exam Gloves, 12" length, X-Small | 500 |
| 50601 PURPLE NITRILE* Exam Gloves, 12" length, Small | 500 |
| 50602 PURPLE NITRILE* Exam Gloves, 12" length, Medium | 500 |
| 50603 PURPLE NITRILE* Exam Gloves, 12" length, Large | 500 |
| 50604 PURPLE NITRILE* Exam Gloves, 12" length, X-Large | 500 |
| 55080 PURPLE NITRILE* Exam Gloves, X-Small | 1,000 |
| 55081 PURPLE NITRILE* Exam Gloves, Small | 1,000 |
| 55082 PURPLE NITRILE* Exam Gloves, Medium | 1,000 |
| 55083 PURPLE NITRILE* Exam Gloves, Large | 1,000 |
| 55084 PURPLE NITRILE* Exam Gloves, X-Large | 900 |

| STERLING* Nitrile Exam Gloves / Good barrier protection where fluid exposure is low to moderate | Eaches/Case |
|---|---|
| 53137 STERLING* NITRILE Exam Gloves, 12" length, X-Small | 1,000 |
| 53138 STERLING* NITRILE Exam Gloves, 12" length, Small | 1,000 |
| 53139 STERLING* NITRILE Exam Gloves, 12" length, Medium | 1,000 |
| 53140 STERLING* NITRILE Exam Gloves, 12" length, Large | 1,000 |
| 53141 STERLING* NITRILE Exam Gloves, 12" length, X-Large | 1,000 |
| 50705 STERLING* NITRILE Exam Gloves, X-Small | 2,000 |
| 50706 STERLING* NITRILE Exam Gloves, Small | 2,000 |
| 50707 STERLING* NITRILE Exam Gloves, Medium | 2,000 |
| 50708 STERLING* NITRILE Exam Gloves, Large | 2,000 |
| 50709 STERLING* NITRILE Exam Gloves, X-Large | 1,700 |

| MICROCOOL* Surgical Gowns – AAMI Level 4 / Liquid Barrier Protection | Eaches/Case |
|---|---|
| 72438 MICROCOOL* Breathable High Performance Surgical Gown, Non-Sterile, Large | 40 |
| 72445 MICROCOOL* Breathable High Performance Surgical Gown, Non-Sterile, X-Large | 32 |
| 72447 MICROCOOL* Breathable High Performance Surgical Gown, Non-Sterile, XX-Large | 32 |

| ULTRA Film Reinforced Surgical Gowns – AAMI Level 4 / Liquid Barrier Protection in the Critical Zones | Eaches/Case |
|---|---|
| 74411 ULTRA Film-Reinforced Surgical Gown, Non-Sterile, Large | 40 |
| 74421 ULTRA Film-Reinforced Surgical Gown, Non-Sterile, X-Large | 32 |

| Footwear | Eaches/Case |
|---|---|
| 69571 HI GUARD* Regular Full-Coverage Boot, Universal | 150 |
| 69671 HI GUARD* Regular Full-Coverage Boot, X-Large | 150 |
| 69572 HI GUARD* Ultra Coverage Boot, Universal | 120 |
| 69672 HI GUARD* Ultra Coverage Boot, X-Large | 120 |

| Isolation Gowns – AAMI Level 2 / For when expected risk of exposure to fluid is between low and moderate | Eaches/Case |
|---|---|
| 69979 CONTROL* Cover Gown with Elastic Cuffs, Yellow, Universal | 100 |
| 69988 CONTROL* Cover Gown with Elastic Cuffs, Yellow, X-Large | 100 |

**KIMBERLY-CLARK***
**Personal Protective Equipment**

| Back Table Covers – Heavy Duty and Reinforced (Impervious) | Current Case UOM |
|---|---|
| 89906 Back Table Cover – Heavy Duty, 60" X 90", Sterile | 28 |
| 89908 Back Table Cover – Heavy Duty, 70" X 110", Sterile | 15 |
| 79060 Back Table Cover - Reinforced, 60" X 60", Non-Sterile | 800 |
| 79006 Back Table Cover – Heavy Duty, 60" X 90", Non-Sterile | 400 |
| 79008 Back Table Cover – Heavy Duty, 70" X 110", Non-Sterile | 280 |
| 29245NS Back Table Cover – Heavy Duty, 60" X 90", Fan Fold, Non-Sterile | 240 |
| 29246NS Back Table Cover – Heavy Duty, 70" X 110", Fan Fold, Non-Sterile | 176 |

| Preparation Pads (If absorption is needed with floor pads.) | Eaches/Case |
|---|---|
| 79713 Extremity Prep Pad, Bulk Pack | 65 |

For more information, please contact your Kimberly-Clark sales representative, or visit www.kchealthcare.com or www.kcprofessional.com. You may also contact Kimberly-Clark Health Care at 1-800-KCHELPS or Kimberly-Clark Professional at 1-800-241-3146.

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# Exhibit F

# Kimberly-Clark Ebola Virus Disease (EVD) Precautions Brief: September 19, 2014

**EBOLA:** The Ebola virus is a lipid enveloped virus in the family Filoviridae. Members of this family also include Marburg, Lassa, and other viruses that cause hemorrhagic fever, a group of illnesses that damage the vascular system and in severe cases, lead to bleeding under the skin, in internal organs or from body orifices (e.g. mouth, eyes and ears)[1]. Infection with the Ebola virus is now referred to as: Ebola virus disease (EVD)[2]. There is a diagnostic test to determine if the patient has EVD. There is no current FDA approved effective medication or treatment for those who become infected with Ebola other than supportive hydration, electrolyte balancing and oxygen. The death rate of those infected is between 50-90%. There is no vaccine or preventative treatment.

## TRANSMISSION

Person-to-person transmission occurs by very close personal contact with an infected individual or with their body fluids during the late stages of infection or after their death[3,4]. During the care of an infected individual, spread of the virus can occur through contact with infected body fluids on the patient, on their clothes or bedding, on surfaces such as bedrails, side tables, the floor, or on reused unsterilized syringes, needles, thermometers or other virus-contaminated medical equipment. Transmission has occurred by handling the bodies of deceased humans in preparation for funerals[5,6]. Bodies can remain contagious for up to 60 days. Infections may also occur when handling sick or dead non-human primates.

### Virus containing body fluids from individuals infected with the Ebola virus:

- Blood
- Breast milk
- Organs and tissues
- Saliva
- Semen
- Stool
- Sweat
- Urine
- Vaginal secretions
- Vomit
- Amniotic fluid (possibly)

**Note:** Ebola virus has been isolated from semen 61 days after the initial symptoms of infection appear. Transmission through semen has occurred 7 weeks after clinical recovery[3,4,7].

**Incubation period:** It requires 2 to 21 days (more often 4-9 days) before symptoms of infection occur. The infected individual is not contagious until symptoms appear. Hemorrhage begins to present 4-5 days after general symptom onset[8,9].

**Survival outside the body:** The virus can survive and remain infective in liquid or dried organic matter at room temperature for a number of days[10]. A 2010 study recovered infective Ebola virus from an indoor environment six days after contamination (under optimal conditions for viral survival) [11]. The Ebola virus can also survive for several days at 39°F (4°C), and is indefinitely stable at -70°C. Infectivity can be preserved by lyophilization (freeze-drying)[5,29].

**How Ebola enters the body:** Intact skin is a barrier, but scratches, cuts (large or tiny), rashes, and abrasions, ruin the barrier integrity and become routes for viral entry. Additionally, Ebola virus can enter the body through mucosal tissues after being deposited by contaminated fluids through physical contact, splashes, splatters,

sprays, or possibly aerosols. Mucosal tissues include the eyes, mouth, throat, lungs inside of nose, vaginal tissues, intestines, and urinary tract[3,4].

**Aerosols:** Infections have occurred after handling sick or dead infected non-human primates and the bodies of deceased humans in preparation for funerals. It is possible transmission could have occurred through aerosol droplets[3,4,5]. Small-particle aerosol exposure and transmission has been demonstrated in non-human primates in the laboratory[2,4].

**Infectious dose:** 1 – 10 aerosolized infective viruses are enough to cause an infection in humans[12].

**Preventing the spread of Ebola virus requires preventing contact with the virus by:**

- Immediate isolation for patients who are confirmed or suspected of being infected with the Ebola virus.
- Protecting all the routes of entry into the body with appropriate personal protective equipment (PPE) as described below.
- Disinfecting, sterilizing or in any other effective way, destroying the viruses that may be contaminating surfaces, medical instruments, linens, etc., before they can contaminate and infect anyone else.
- Properly containing the body of deceased victims in fluid proof body bag and appropriately cremating or burying them immediately.

## IMMEDIATE ISOLATION OF SUSPECTED OR CONFIRMED EVD PATIENT:

- Immediately place patient in a private room with personal toilet facilities and implement strict Standard, Contact, and Droplet precautions.
- The mattress and pillow must be fluid resistant.
- All devices used must be disposable or dedicated. If dedicated but to be used after patient discharge, a thorough disinfection must be completed. A week of post-disinfection quarantine if possible is an added safety measure as no reports of Ebola virus survival longer than 6 days have ever been reported.
- Avoid aerosol generating procedures if at all possible. If aerosol generating procedures are anticipated, place patient in an airborne isolation room initially to avoid patient transport, and wear a fluid resistant N95 respirator or greater when performing these procedures.

## PERSONAL PROTECTION

- Make certain scratches, cuts, rashes, abrasions, etc., are covered with waterproof dressings.
- Remove jewelry
- The United States Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO) recommend masks for protection from Ebola as part of Standard, Contact, and Droplet protection. Though not stated in the guidelines, **it is critical that masks are fluid resistant** to prevent splashes, sprays and cough-propelled droplets of virus-contaminated blood, saliva or other body fluid from penetrating the mask.
    - Because of the life-threatening nature of this disease, if a mask is worn, it should have an **ASTM F2100 Level 3 designation: the highest fluid penetration and filtration efficiency level.** The Level will be listed on the box label[13,14,15]. ASTM Levels 1 or 2 could be used outside the Ebola isolation area.
    - To qualify for each ASTM designation, the mask material must also pass a particle filtration test with a challenge of 0.1 micron particles. However, this challenge size represents airborne particles that can float on air currents and be sucked through the gaps between the mask and the face when the wearer inhales. Although any mask with an ASTM Level Designation has

passed this o.t micron challenge, the test is not included in chart below for fear it will give the wearer or purchaser a false sense of security that a medical mask will protect against very small droplets. If anticipating exposure to small infectious aerosols, a fluid resistant respirator of N95 or greater designation must be worn.

| Mask: ASTM F2100 Spray, Splatter, Droplet Protection Level Designation (Level 3 highest) | | |
|---|---|---|
| **Level** | **Test Description** | **Must Pass** |
| 3 | ASTM F1862 Pressure spray synthetic blood: simulates high blood pressure<br>ASTM 2101 Bacterial Filtration Efficiency (droplet) | 160mm Hg<br>≥98 |
| 2 | ASTM F1862 Pressure spray synthetic blood: simulates normal blood pressure<br>ASTM 2101 Bacterial Filtration Efficiency (droplet) | 120mm Hg<br>≥98 |
| 1 | ASTM F1862 Pressure spray synthetic blood: simulates systolic blood pressure<br>ASTM 2101 Bacterial Filtration Efficiency (droplet) | 80mm Hg<br>≥95 |

- **Note:** When an Ebola virus infected patient is in the late stages of EVD, blood pressure will drop, but other sources of propelled fluids, including diarrhea and vomit, contain the infective virus and can be delivered with force. Fluid resistance is still essential.

- **Respirators.** CDC is recommending face masks; avoiding aerosol generating procedures, and; wearing a respirator if aerosol generating cannot be avoided. As noted, there have been studies and observations demonstrating a potential small droplet dispersal component of Ebola virus transmission[2,3,4,5]. The highest probability of generating small droplets presenting the highest risk would occur during aerosol generating procedures, but should also be considered a risk during care of late stage EVD patients. Because disposable respirators are designed to prevent gaps in the respirator-to-face seal, small infectious droplets cannot be drawn into the mucosa-lined respiratory zone through mask-face skin gaps (area of least resistance) when the wearer inhales. A mask does not provide that seal and thus pulls a portion of inhaled air in through the gaps. The virus may land on the inside surface of the mask, the facial skin, or oropharyngeal mucosa. Respirators must be fit tested to the wearer, ensuring the size and model fit snugly[16]. ***Every time a disposable respirator is donned, the wearer must immediately perform a seal check[17]. This critical verification takes only seconds. As with masks, respirators must also be fluid resistant for the same reason (wick-through; strike-through).***

  - **Avoid aerosol generating procedures.** *Avoid aerosol-generating* procedures if at all possible. If they must be performed, PPE must include an N95 respirator or higher level respiratory protection). Procedure should be performed in an airborne infection isolation room[18].

  - **Note:** Some respirators possess staples in the filtration portion of the respirator. After the stress of use, holes can develop where the staples penetrate the fabric. This will not necessarily be detected during fit tests as the respirator has not yet been in actual use, subjected to the continual pull of the elastic attached to the staples.

- **Eye protection or face shield is essential.** If eye contamination suspected, rinse eyes immediately & excessively with saline or water. *Face shields do not take the place of face masks or respirators.*

- **Gowns or coveralls.** CDC recommends wearing a fluid resistant (front and back) gown or coverall with snug-fitting cuffs. ANSI/AAMI PB70:2012[19] sets requirements for different performance levels. Level 4 is

the most protective and would be appropriate for working with Ebola patients, especially in the late stages of the disease. The lower fluid resistant levels are appropriate for Standard, Contact and Droplet precautions dealing with less lethal pathogens. For high exposure risk, a full body suit with Level 4 verified testing and adequate coverage would be appropriate.

| ANSI/AAMI PB70:2012 The Most protective is Level 4 | | | |
|---|---|---|---|
| Level | Test ID and description | Required | What's better |
| 4 | ASTM F1670:Penetration by forced spray synthetic blood<br>ASTM F1671:Bloodborne pathogen penetration: bacteriophage virus in fluid pressed through | Pass<br>Pass | Pass<br>Pass |
| 3 | AATCC 42:Spray impact – amount penetrated after fluid drop impact<br>AATCC 127:Hydrostatic pressure – pressure needed to force water through | < 1.0g<br>≥ 50cm | Lower<br>Higher |
| 2 | AATCC 42:Spray impact – amount penetrated after fluid drop impact<br>AATCC 127:Hydrostatic pressure – pressure needed to force water through | ≤ 1.0g<br>≥ 20cm | Lower<br>Higher |
| 1 | AATCC 42:Spray impact – amount penetrated after fluid drop impact | ≤ 4.5g | Lower |

- **Severe exposure:** For situations in the field or other similar conditions dealing with high levels of viral contamination and fluids, a full body fluid-resistant certified biohazard suit should be worn.

- **Head covers.** During later stage EVD, virus-contaminated droplets can fall onto exposed hair. When contaminated hair is touched, the hand can become contaminated and transport the virus to other places on the individual or to other animate and inanimate surfaces in the environment. Although not specified in many guidelines, wearing a fluid-resistant head cover while insuring the maximum amount of head, neck, and face coverage is achieved would be best practice within the Ebola isolation unit during late stage EVD.
  - **Note:** If coverage is not complete, wash exposed areas of the face and neck with soap and water to remove any contamination after tasks are completed or if contamination has occurred. Consider 70% alcohol wipe thereafter.

- **Foot/leg covers.** For additional protection during the late EVD stage, fluid resistant foot/leg covers can protect footwear and legs from contamination and prevent transporting the virus to others when the patient is in the late stages of EVD (bleeding, diarrhea, vomiting) when likelihood of fluid contamination is high, during patient fluid cleanup, etc.

- **Gloves.** Examination or surgical gloves as appropriate:
  - All gloves must be powder-free. Virus can readily contaminate powder particles and be dispersed throughout the vicinity as do glove powder particles.
  - Neither vinyl nor polyethylene gloves are appropriate for barrier protection when performing tasks with potentially infectious materials.

- Good barrier powder-free gloves include nitrile, natural rubber latex, polyisoprene, and neoprene. In some situations, a medical glove beneath a thick orthopedic type surgical glove may be appropriate for procedures on a patient, or new thick utility glove as for cleaning.
- Double glove, making certain one glove is under the gown cuff and the other glove is over the cuff. It may be prudent to tape the glove to the cuff with duct tape to prevent cuff slip or roll down.

- **Be extremely careful not to disperse viral contaminants during PPE removal.** Assume outward facing surface of all PPE are contaminated with infectious Ebola. It is preferred that assistance in PPE removal is given by a designated individual who is scrupulously appareled and trained in appropriate PPE removal techniques, biohazard bag processing, disinfection of the area, etc. A written procedure should be clearly posted.
- **Hand hygiene.** Wash hands with soap and water immediately after removing PPE. Soap and water are recommended due to the amount of organic contamination (blood, vomit, etc.) present that can interfere with the efficacy of alcohol hand sanitizers. Soap helps organics and the virus slip off, and water rinses them into the sewage system where they are effectively destroyed by standard sewage treatment procedures.
  - **Note:** If caring for patients in an area without sewage treatment, wash with soap and water into a basin. After finishing, add 1 part household bleach to 10 parts of the water (10% v/v) in the basin to destroy any remaining infective virus. Hold for 10 minutes before assuming disinfection is complete.
- **70-90% ethyl alcohol (ethanol) based hand sanitizers** will destroy lipid enveloped viruses like Ebola very effectively if the organic soiling is not present. This higher concentration than normally recommended is appropriate for disinfecting non-enveloped viruses including Norovirus, thus providing an added safety factor for the more easily disinfected enveloped Ebola virus. (See further rationale for this non-enveloped virus safety factor in the Surface Disinfection section.) The alcohol based hand sanitizer can also be used after a soap and water wash first to remove organic matter (soiling), if present.

## SURFACE DISINFECTION IS CRITICAL TO PREVENTING THE SPREAD OF EBOLA

The Ebola virus can stay infective for up to 6 days on surfaces in ideal conditions[10,11]. Attention to rigorous disinfection practices is essential. Fortunately, the virus is destroyed by most standard disinfectants used in healthcare[5,28,29,30,31]. However, because of the severe morbidity and high mortality risk posed by the virus, the high number of infective viruses in the blood during the late stages of the disease, the extremely low number of Ebola virus required to cause an infection, and the probable high level of organics presence in body fluid spills and splatters, higher disinfectant concentrations than normally used in standard healthcare environmental cleaning are appropriate.

In the United States, healthcare facilities are to use Environmental Protection Agency (EPA)-registered hospital disinfectants with a label claim for a non-enveloped (a.k.a hydrophilic) virus (e.g., norovirus, rotavirus, adenovirus, poliovirus) to disinfect surfaces in rooms of patients with suspected or confirmed Ebola virus infection. There are no specific label claims against Ebola. However, because it is much harder destroy non-enveloped viruses than it is enveloped viruses (a.k.a hydrophobic) like Ebola, the use of disinfectants with a label

claim of being effective against non-enveloped viruses will be effective against the Ebola virus while providing an added safety margin.

In situations or countries where EPA approved disinfectants against non-enveloped viruses (viruses much harder to destroy than enveloped viruses including Ebola) are not available, select disinfectants proven to be effective against non-enveloped viruses by recognized agencies.

If such approved disinfectants for non-enveloped viruses are not available, household bleach (hypochlorite at 5.25% to 6.25%) can be diluted to a working concentration appropriate for Ebola virus disinfection.

> **Important:** *The effectiveness of many disinfectants, including hypochlorite, are weakened or inactivated by the presence of organic contamination of the surface to be disinfected*[20,21]. Organic substances in this context include blood, vomit, feces, pus and sputum. Normally, cleaning with a detergent first to remove the organic contamination would be recommended. However, to reduce the risk of staff infection during clean-up procedures, a higher concentration of the disinfectant can reduce the viral load despite inactivation of a percentage of the disinfecting free chlorine. For example, hypochlorite is usually used at a working concentration of 100-500ppm chlorine for routine hospital disinfection, after cleaning with a detergent to remove organic matter. However, if heavily soiled with organic matter potentially containing Ebola (high lethality; high viral concentration in blood; very few viruses necessary for infection), a 1:10 solution of hypochlorite (household bleach) is appropriate (1 part bleach to 10 parts water v/v). This is equivalent to 5,000ppm chlorine. Another way to make this concentration is to add 1⅓ cups household bleach to one gallon of water. Because the effectiveness of diluted hypochlorite decays over time, working solutions should be prepared fresh every 24 hours[22,23].
>
> **Important:** *Paper and cotton are cellulose based materials. Cellulose reduces the effectiveness of hypochlorite and hydrogen peroxide.* Higher concentrations of the disinfectant can compensate. Do not leave paper towels or cotton cloths in open cleaning bucket containing diluted hypochlorite, for example, as the effective concentration of chlorine will diminish significantly[24,25]. The use of polypropylene wipes or wipes that contain coated cellulose specifically treated to prevent disinfectant inactivation and absorption exist but must be confirmed with official data from the manufacturer.
>
> **Important:** Do not mix hypochlorite (bleach) with other cleaning agents (e.g. ammonia) as toxic fumes can be produced injuring healthcare staff and patients[26,27].

**A written policy and procedure should be in place to address removal and cleaning of large spills or otherwise deposited, fluid-contaminated areas as well as for biohazard bag processing.** The following example will discuss the use of hypochlorite, but other regulated disinfectants proven effective against non-enveloped viruses (as detailed above) are appropriate when available. For example, such an EPA approved disinfectant is required for healthcare facilities in the U.S.

1. Don appropriate PPE as described above, including fluid resistant foot and leg covers.
2. Use forceps to pick up any syringes, needles or other instruments from the spill prior to disinfection and place in impenetrable container to prevent accidental injury during cleanup.
3. Gently place paper towels over the contaminated fluid to avoid splatter and absorb contaminated fluid.
4. Carefully apply a 1:10 final dilution of household bleach (5,000ppm to overcome the cellulose and organic matter) starting at the perimeter and working towards the center[20,21,22].

5. Allow sufficient contact time which depends on the disinfectant, its concentration, and the amount and nature of the spill. For a 1:10 dilution of hypochlorite, with minimal fluid dilution from the contaminated surface, 10 minutes is sufficient[40].
6. After the label-required contact time, remove the saturated towels carefully and place into biohazard bags. Absorb any remaining fluid with additional paper towel and dispose into the biohazard bag. Assume the paper towels are still contaminated (extra precaution for the high-lethality and low infectious dose of this pathogen). Assuming the exterior of the biohazard bag to be contaminated and place in a rigid container to prevent re-contamination of the area and for later transport.
7. Now disinfect the area again, freed of the organic load and cellulose absorbing cover paper towels. This time the lower working concentration of 1:100 (500ppm free chlorine) would be effective, but the same 1:10 working solution (5,000ppm free chlorine) provides an added safety factor. The working hypochlorite solution may be poured onto the surface or spread with a polypropylene wipe or other approved wiper demonstrated to not absorb or inactivate the biocidal free chlorine. Wait for the required contact time. Place used wipes in biohazard bags as noted above.
8. Rinse disinfected surface with water after disinfection is completed to reduce damage to surfaces and remove the strong chlorine odor that can adversely affect already nauseated patients[22,9].
9. Steam sterilize (autoclave), incinerate biohazardous waste, or present for disposal by specialized biohazard team. Follow state or local regulations for handling biohazard waste disposal.

Note: The Ebola virus is destroyed by both steam sterilization and incineration. There will be no infectious viruses in the exhaust steam or incineration smoke.

**Physical destruction:** Ebola virus are also inactivated by:

- Heating for 30 to 60 minutes at 140°F (60°C)
- Boiling for 5 minutes
- Gamma irradiation (1.2 x$10^6$ rads to 1.27 x$10^6$ rads)
- UV radiation [5,28,29,30,31] However, it is important to note, Ebola viruses incorporated within organic matter can survive can survive UV radiation[32].

**LABORATORY SAFETY**

**Biosafety level:** Ebola is a Group 4 pathogen with an infectious dose of 1 to 10 inhaled viruses. There can be no shortcuts to protection.

**Laboratory-acquired infections:** There are many opportunities for accidents to occur in the laboratory. One reported near-fatal Ebola case followed a minute finger prick in an English laboratory[33]. A Swiss zoologist contracted Ebola virus after performing an autopsy on a chimpanzee in 1994[4,34]. In 2004, a similar case was reported in the United States[35], and a fatal case in Russia[36]. The Marburg virus is morphologically indistinguishable from the Ebola virus. In 1967, 31 workers at a laboratory in Marburg, Germany suffered from fever, diarrhea, vomiting, and massive bleeding from a variety of internal organs due to infection from the Marburg virus. Seven of the workers would eventually succumb to their infection[37].

**Primary hazards in the laboratory:** Accidental inoculation, inhalation of infectious aerosols and droplets, and/or direct contact of specimen, homogenates, dilutions, etc., with broken skin, rashes or mucous membranes including eyes, nares, mouth, and lungs. Use a certified Class II Biosafety cabinet or Plexiglas splash guard with PPE to protect skin and mucous membranes as noted in the PPE above when working with the specimen of

suspected or confirmed EVD patients. All manufacturer-installed safety features for laboratory instruments should be used.

> **Important:** Experimental work with Ebola virus is not addressed in this document. Experimental work often utilizes increased viral concentrations and extensive manipulations requiring a Containment Level 4 facility[3,4,38,39].

**Protective clothing:** Personnel entering a laboratory actively working with suspected Ebola specimen should remove jewelry and street clothing to change into dedicated laboratory clothing and shoes, or don full coverage protective apparel (i.e., completely covering all street clothing). Additional protection may be worn over laboratory clothing when infectious materials are directly handled. This protection includes items such as solid-front, and fluid resistant gowns with tight fitting wrists, gloves, and fluid resistant respiratory protection. A fluid-resistant respirator, N95 or greater, is necessary for any task that could generate aerosols. AVOID aerosol generation procedures if at all possible. Eye protection must be used where there is a known or potential risk of exposure to splashes or sprays[40]. Shoe and legging covers should be worn if there are spills to be disinfected or risk of splatter or spray.

**Sources/specimens:** Sources of the virus include blood, serum, urine, respiratory and throat secretions, semen, organs and tissues or their homogenates from human or animal hosts[3,4,39].

**Transporting specimens within the hospital or institution:** Per CDC, and in compliance with 29 CFR 1910.1030, specimens should be placed in a durable, leak-proof secondary container for transport within a facility. To reduce the risk of breakage or leaks, do not use any pneumatic tube system for transporting suspected EVD specimens. If necessary to hold specimen, they should be refrigerated at 2°-4°C, with all containment requirements in place.

**Preparing specimen for transport:** CDC has an Ebola specific laboratory specimen handling, packing and shipping instruction alert to which laboratories must comply. The CDC Guideline: Case Definition for Ebola Virus Disease (EVD), can be accessed at: http://www.cdc.gov/vhf/ebola/hcp/interim-guidance-specimen-collection-submission-patients-suspected-infection-ebola.html . No specimen will be accepted by the FDA without prior consultation. For consultation call the CDC's Emergency Operations Center (EOC) at 770-488-7100.

For more information and updates, please refer to subject matter expert websites that include those found in the Resources section of this document.

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