

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION**

MEDLINE INDUSTRIES, INC.

Plaintiff,

v.

C.R. BARD, INC.

Defendant.

Civil Action No. _____

JURY TRIAL DEMANDED

**PLAINTIFF MEDLINE INDUSTRIES, INC.’S
COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff Medline Industries, Inc. (“Medline”), by counsel, alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement. Medline brings this action to enjoin the manufacture, use, sale, offer to sell, and importation by Defendant C.R. Bard, Inc. (“Bard”) of products that infringe a valid and enforceable U.S. patent owned by Medline, and for monetary damages for Bard’s infringement.

THE PARTIES

2. Plaintiff Medline is a corporation organized under the laws of the State of Illinois and headquartered in Northfield, Illinois. Medline manufactures

and distributes more than 550,000 health care supplies and services across the continuum of care.

3. Medline leads the market in more than a dozen major medical product categories, including exam gloves, textiles, durable medical equipment, plastic patient utensils, skin care, disposable incontinence care, protective apparel, disposable drapes and gowns, and surgical procedure trays.

4. Medline's customers include hospitals, nursing homes, surgery centers, physician offices, home care providers, home health agencies, and retail outlets. Medline has 40 distribution centers in North America and 50 throughout the world. In addition, it has 17 manufacturing facilities worldwide.

5. Founded in 1966, Medline's roots date back to 1910, when A.L. Mills, the great-grandfather of the current leadership, sewed butcher's aprons in Chicago. Medline has grown from a small manufacturer of aprons, surgical gowns, and uniforms to a thriving \$8 billion global enterprise because of its dedicated employees, entrepreneurial spirit, and honest values. The company has grown into America's largest privately held national manufacturer and distributor of health care supplies and services.

6. In 2019, Forbes Magazine ranked Medline in the top 50 of largest privately held companies in America. Medline employs more than 24,000 colleagues worldwide, with operations in more than 90 countries.

7. Defendant Bard is a corporation organized under the laws of the State of New Jersey, and having a principal place of business at 730 Central Avenue, Murray Hill, New Jersey 07974.

8. Bard Medical Division, a division of Bard, is headquartered at 8195 Industrial Blvd., Covington, Georgia, within this judicial district.

JURISDICTION AND VENUE

9. This is a civil action for patent infringement arising under the United States patent statutes, 35 U.S.C. § 1 et seq.

10. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

11. Bard's employees designed, developed, engineered, and developed a marketing strategy for the SureStep Foley Kit accused of infringement in this case at Bard's facilities in Covington, Georgia.

12. Bard's employees receive customer orders, consummate sales, and coordinate the distribution of the SureStep Foley Kit accused of infringement in this case at Bard's facilities in Covington, Georgia.

13. Bard's employees at Bard's facilities in Covington, Georgia oversee production and manufacturing specifications for the SureStep Foley Kit accused of infringement in this case.

14. The SureStep Foley Kits accused of infringement in this case are sterilized at Bard's Global Distribution Center in Covington, Georgia.

15. Defendant Bard is subject to this Court's personal jurisdiction because it does and has done substantial business in this judicial district, including designing, developing, engineering, sterilizing, marketing, distributing, selling, and offering to sell in this judicial district the SureStep Foley Kit accused of infringement in this case.

16. Bard is also subject to the general jurisdiction of this Court because it has regular and systematic contacts with this forum such that the exercise of jurisdiction over it would not offend traditional notions of fair play and substantial justice.

17. Venue is proper in this judicial district because Bard has committed acts of infringement in this judicial district, and Bard has a regular and established place of business physically located in Covington, Georgia, within this judicial district.

18. Venue is also proper in this judicial district because Bard itself has argued that “venue is proper in the Northern District of Georgia” in a patent infringement case involving the same parties, same accused products, and related patents.

BACKGROUND

19. A urinary catheter is a thin tube placed in the bladder to drain urine. A Foley catheter is a type of indwelling urinary catheter that is held inside the bladder with an inflatable balloon. The urine drains through a tube into a collection bag. If sterility of the catheter is compromised prior to insertion, it is possible for germs to travel along the catheter, which can result in a catheter-associated urinary tract infection (a.k.a. “CAUTI”).

20. At the time of the invention claimed in the Patent-in-Suit, catheters were a common feature of hospital care, used by over four million hospital patients a year. Another, but seldom-discussed, reality was that the chances of a patient getting a CAUTI were not insignificant. In fact, the daily risk for patients acquiring a urinary infection was as high as seven percent when indwelling urethral catheters remained in their original position. Overall, such infections accounted for more than one third of all hospital-acquired infections.

21. The cumulative impact of these CAUTIs was indeed significant, as they raised hospital costs, increased a patient's stay, and complicated recovery. CAUTIs were a major drain on hospital resources, increasing the length of a hospital stay by between one and three days on average. At the time of the invention, such infections added approximately \$675 per patient to the costs of hospitalization. The Centers for Medicare & Medicaid Services ("CMS") reported that in 2007, patients with CAUTIs incurred an average cost of \$44,043 per hospital stay.

22. Yet despite this, clinicians often gave minimal thought to the decision to insert a Foley catheter, its optimal management, or its timely removal. Supporting data also suggested that many times a urinary catheter was inserted without a physician's order, and that at times patients were not assessed appropriately for alternatives to catheterization.

MEDLINE'S INVENTION

23. Medline rose to the challenge and worked to devise a solution to reduce the incidence of CAUTIs. As part of that effort, and at significant expense, Medline set out to understand the issues related to CAUTI prevention and the shortcomings of Foley catheter trays as they existed at that time.

24. In 2009, Medline designed the industry's first single-layer Foley catheter tray (the "Medline Tray") to reduce the risk of CAUTI. Medline further developed methods using catheter tray assemblies in a manner that reduced the risks of CAUTI. The invention was in direct response to long-felt clinician-identified product deficits. Customers that were looking to fill those gaps responded very well to the invention and have become champions for the Medline Tray. The Medline Tray is marketed under the trade name "ERASE CAUTI." The "ERASE" portion of the product name is an acronym for best practices in a Foley catheterization procedure: Evaluate indications; Read instructions; Aseptic technique; Secure catheter; and Educate patient.

25. Before the inventions claimed in the Patent-in-Suit, conventional Foley catheter kits were two-layer kits. The base or lower layer of the kit held the drainage receptacle, tubing, and Foley catheter. The upper tray of the kit held patient preparation components. This traditional design made it difficult to maintain a sterile field and keep the catheter aseptic while performing the procedure. In the field, many practitioners would, to access the components in the lower tray, place the upper tray outside the sterile field, thus increasing the risk of CAUTI.

26. The inventors designed the single-layer urinary catheter tray of the Patent-in-Suit to minimize the risk of contaminating the patient or compromising the sterile field during the catheterization procedure. By having easy access to the components in a single-layer tray (rather than a dual-layer kit), the clinician can now more easily prepare and use the components within the kit/tray. Additionally, the inventors conceived of step-by-step educational instructions to reinforce that the components of the tray are accessible from top to bottom and/or left to right, in the order in which they are required in the catheterization procedure.

27. Medical facilities that purchased Medline's patent-protected ERASE CAUTI trays experienced immediate positive results.

28. Medline began selling its patent-protected ERASE CAUTI trays in 2009 and experienced success over the ensuing months and years, growing its market share.

29. Pharmaceutical & Medical Packaging News reported on Medline's ERASE CAUTI tray in March 2010, touting the tray as follows:

Medline Industries Inc.'s (Mundelein, IL) novel Foley catheter management system is a revolutionary approach to managing catheters and reducing catheter associated urinary tract infections (CAUTI). The shift from a two-layer tray to a one-layered tray to support the sequence of events during catheterization represents a major change for clinicians within the hospital setting. The product launched alongside a comprehensive professional awareness campaign, ERASE CAUTI, using

packaging that includes a patient and family education components. Developed by Deborah Adler and Medline's urological product division and marketing division, the one-layer tray design encourages aseptic technique.

30. Pharmaceutical & Medical Packaging News interviewed physicians and nurses that had used the ERASE CAUTI tray. They reported, “As educators at our facility, we were really impressed with the new Medline catheter tray design to help prevent CAUTI,” says Becky Schlabach RN, CNOR, Perioperative Educator, Goshen General Hospital (Goshen, IN). ‘Medline has really done their homework on what nurses need and how to render great patient care. The tray is very intuitive, and our colleagues were pleased with and sold on the product from the first use. This is a great product from a great company.’”

31. Medline practices the claimed inventions. A list of Medline products covered by the invention of at least claim 1 of the Patent-in-Suit is attached as Exhibit B.

BARD REACTS

32. On information and belief, Bard, Medline's primary competitor in the Foley catheter tray market, recognized the competitive threat posed by Medline's patent-protected ERASE CAUTI trays and began to react.

33. In 2010, Bard redesigned its dual-layer Foley catheter kit and began selling a new dual-layer kit, which it called Advance. The Advance tray was

designed as a response to Medline's ERASE CAUTI trays and copied certain elements of Medline's ERASE CAUTI product and program. However, the Advance tray maintained the problematic two-layer structure that had defined conventional Foley catheter trays for years.

34. In 2014, five years after Medline developed its patent-protected ERASE CAUTI trays that featured a single-layer design, Bard began selling the copycat single-layer SureStep Foley Kit ("the Original SureStep Foley Kit").

35. On information and belief, the Original SureStep Foley Kit was the first single-layer Foley catheter tray developed and/or sold by Bard.

36. On information and belief, Bard developed the Original SureStep Foley Kit in response to the competitive threat of Medline's patent-protected ERASE CAUTI trays.

37. On information and belief, Bard copied Medline's single-layer design in developing the Original SureStep Foley Kit.

38. At the time of launch, Bard's Original SureStep Foley Kit included instructions with a health care services portion and a detachable patient portion. On information and belief, later in 2014 Bard changed the instructions to separate the health care services portion and patient portion in an attempt to avoid

infringement of Medline patents, including but not limited to claim 2 of the Patent-in-Suit.

39. Medline's ERASE CAUTI tray includes an opening in the barrier wall between the compartment containing the catheter, tubing, and drainage receptacle, and the compartment containing syringes. The tray in Bard's Original SureStep Foley Kit also contained an opening in the barrier wall between the compartment containing the catheter, tubing, and drainage receptacle, and the compartment containing syringes.

40. In early 2016, Bard began selling a version of the SureStep Foley Kit ("the Current SureStep Foley Kit") with a redesigned tray with no opening in the barrier wall between the catheter and syringe compartments.

41. The Current SureStep Foley Kit is offered in a number of variants, including two different tray sizes to accommodate different drainage receptacles, and with different catheter sizes and materials. For purposes of this Complaint, the Current SureStep Foley Kit should be understood to include all SureStep products containing a Foley catheter and including the redesigned tray, including but not limited to the SKUs identified in Exhibit C.

42. On information and belief, Bard redesigned the tray of the Original SureStep Foley Kit to attempt to avoid infringement of other Medline patents, including but not limited to U.S. Patent No. 8,678,190.

43. At the time of this redesign, Bard was aware of Medline's claims of infringement of other Medline patents, including claim 1 of the Patent-in-Suit, but Bard did not redesign its Current SureStep Foley Kit further to attempt to avoid such claims of infringement.

THE PATENT-IN-SUIT

44. In recognition of the innovative features of the Medline Tray, the U.S. Patent and Trademark Office awarded multiple patents to Medline. In addition, Medline has other patents pending that protect the Medline Tray and related methods.

45. On May 28, 2013, the United States Patent and Trademark Office duly and legally issued United States Patent No. 8,448,786 ("the '786 Patent" or the "Patent-in-Suit"), entitled "Catheter Tray, Packaging System, Instruction Insert, and Associated Methods," to Medline. Based on a certificate of correction issued on July 16, 2019, the inventors of the '786 Patent are Jennifer E. Tomes, Sarah Zyburt, Susan MacInnes, and Deborah Adler. A true and correct copy of the '786 Patent is attached as Exhibit A.

46. Medline is the owner by assignment of the entire right, title, and interest in the '786 Patent.

47. Claim 1 of the '786 Patent recites:

A method of using a catheter package assembly, comprising:

opening a thermally sealed bag disposed about a tray having a catheter assembly disposed therein;

accessing an instruction manual;

unfolding one or more layers of wrap to reveal an additional layer of wrap and the catheter assembly; and

placing one of the one or more layers of wrap or the additional layer of wrap beneath a patient, thereby transforming an area beneath the patient from a non-sterile field to a sterile field.

48. Claim 2 of the '786 Patent depends from claim 1 and recites:

The method of claim 1, wherein the instruction manual comprises a health care services portion and a patient portion detachably coupled thereto.

OTHER LITIGATION INVOLVING THE PARTIES

49. On May 16, 2014, Medline filed a complaint for patent infringement in the Northern District of Illinois asserting that Bard infringes certain claims of U.S. Patent Nos. 8,448,786, 8,631,935 and 8,678,190. That litigation, entitled *Medline Industries, Inc. v. C.R. Bard, Inc.*, No. 1:14-cv-03618-JZL-MDW

(“*Medline I*”), is currently pending before the United States District Court for the Northern District of Illinois, Eastern Division.

50. In *Medline I*, Medline also alleges that Bard infringes claim 1 of the ’786 Patent.

51. On December 30, 2014, Bard filed a petition for *inter partes* review of claims 1 and 2 of the ’786 Patent with the Patent Trial and Appeal Board (“PTAB”) of the U.S. Patent and Trademark Office, arguing that the claims were obvious in view of the prior art.

52. On July 15, 2015, the PTAB denied institution of Bard’s *inter partes* review petition, finding that Bard had failed to establish a reasonable likelihood that it would prevail in challenging claims 1 and 2 of the ’786 Patent.

53. On August 10, 2020, the *Medline I* Court ruled that Medline’s infringement claims in *Medline I* are limited to the Original SureStep Foley Kit, and that the Current SureStep Foley Kit is not accused in that case.

54. On March 23, 2016 and on October 5, 2017, Medline filed two additional actions in the Northern District of Illinois asserting that Bard infringes certain claims of other Medline patents in the same family as the Patent-in-Suit. Those litigations, entitled *Medline Industries, Inc. v. C.R. Bard, Inc.*, No. 1:16-cv-03529 (“*Medline IP*”) and *Medline Industries, Inc. v. C.R. Bard, Inc.*, No. 1:17-cv-

07216 (“*Medline III*”), are currently pending before the United States District Court for the Northern District of Illinois, Eastern Division.

55. In *Medline II*, Medline accuses both the Original SureStep Foley Kit and the Current SureStep Foley Kit of infringement. In *Medline III*, Medline accuses the Current SureStep Foley Kit of infringement.

COUNT I: INFRINGEMENT OF THE '786 PATENT

56. Bard has been and is contributorily infringing, and inducing others to infringe claim 1 of the '786 Patent, either literally or under the doctrine of equivalents, by making, using, importing, offering to sell, or selling within the United States products, including but not limited to the Current SureStep Foley Kit, as of the date in 2016 when that product was first made, used, imported, offered for sale, or sold in the United States, including but not limited to the SKUs in Exhibit C.

Notice of Infringement and Willful Infringement

57. Bard, at least as of May 16, 2014, has been aware of the '786 Patent. Bard has been placed on notice of Medline's infringement claims concerning the '786 Patent at least as of the filing of the *Medline I* Complaint.

58. On November 24, 2015, Medline served Bard with Final Infringement Contentions in *Medline I*, explaining in detail how use of the Original SureStep Foley Kit directly infringed claim 1 of the '786 Patent.

59. On information and belief, as of the time Bard redesigned the Original SureStep Foley Kit and began manufacturing and selling the Current SureStep Foley Kit in early 2016, it was apparent to Bard that the use of the Current SureStep Foley Kit by healthcare providers would infringe claim 1 of the '786 Patent.

60. On information and belief, Bard knew that the redesign of the Original SureStep Foley Kit to the Current SureStep Foley Kit did not avoid infringement of claim 1 of the '786 Patent.

61. On information and belief, Bard knew that if the use of the Original SureStep Foley Kit consistent with Bard's instructions for use infringed claim 1 of the '786 Patent, use of the Current SureStep Foley Kit consistent with Bard's instructions for use would also infringe claim 1 of the '786 Patent.

62. On information and belief, at least as of early 2016 when it began selling the Current SureStep Foley Kit, Bard has opted to willfully, deliberately, and intentionally infringe claim 1 of the '786 Patent by making, selling, importing,

and/or offering to sell the Current SureStep Foley Kit, in reckless disregard of Medline's patent rights.

63. On information and belief, at least as of early 2016 when it began selling the Current SureStep Foley Kit, Bard lacked any good faith basis to believe that the '786 Patent was not valid, especially in view of the PTAB's refusal to institute the *inter partes* review Bard filed attacking claim 1 as obvious.

64. For at least these reasons, Bard's knowing inducement of infringement since early 2016 when it began selling the Current SureStep Foley Kit has been willful, deliberate, and consciously wrongful, justifying enhanced damages under 35 U.S.C. § 284.

Indirect Infringement of the '786 Patent

65. Bard is liable for indirectly infringing the '786 Patent by inducing direct infringement in violation of 35 U.S.C. § 271(b) and contributing to direct infringement in violation of 35 U.S.C. § 271(c).

66. Bard has sold, offered for sale and/or marketed the Current SureStep Foley Kit to hospitals and other healthcare providers (collectively, "healthcare providers"), including millions of Current SureStep Foley Kits sold in the United States since early 2016.

67. The Current SureStep Foley Kits are then used by the healthcare providers in a manner that directly infringes claim 1 of the '786 Patent.

68. Bard knows that when healthcare providers use the Current SureStep Foley Kits in their intended manner, such use directly infringes claim 1 of the '786 Patent.

69. Bard provides "Directions for Use" with the Current SureStep Foley Kit. An exemplary copy of the "Directions for Use" for the Current SureStep Foley Kit is attached as Exhibit D hereto.

70. The "Directions for Use" provide a step-by-step explanation of the procedure for properly using the Current SureStep Foley Kit. Bard intends the "Directions for Use" to direct healthcare providers in using the Current SureStep Foley Kit.

71. By providing the "Directions for Use," Bard specifically intends and encourages healthcare providers to directly infringe the '786 Patent.

72. The Current SureStep Foley Kit constitutes a catheter package assembly.

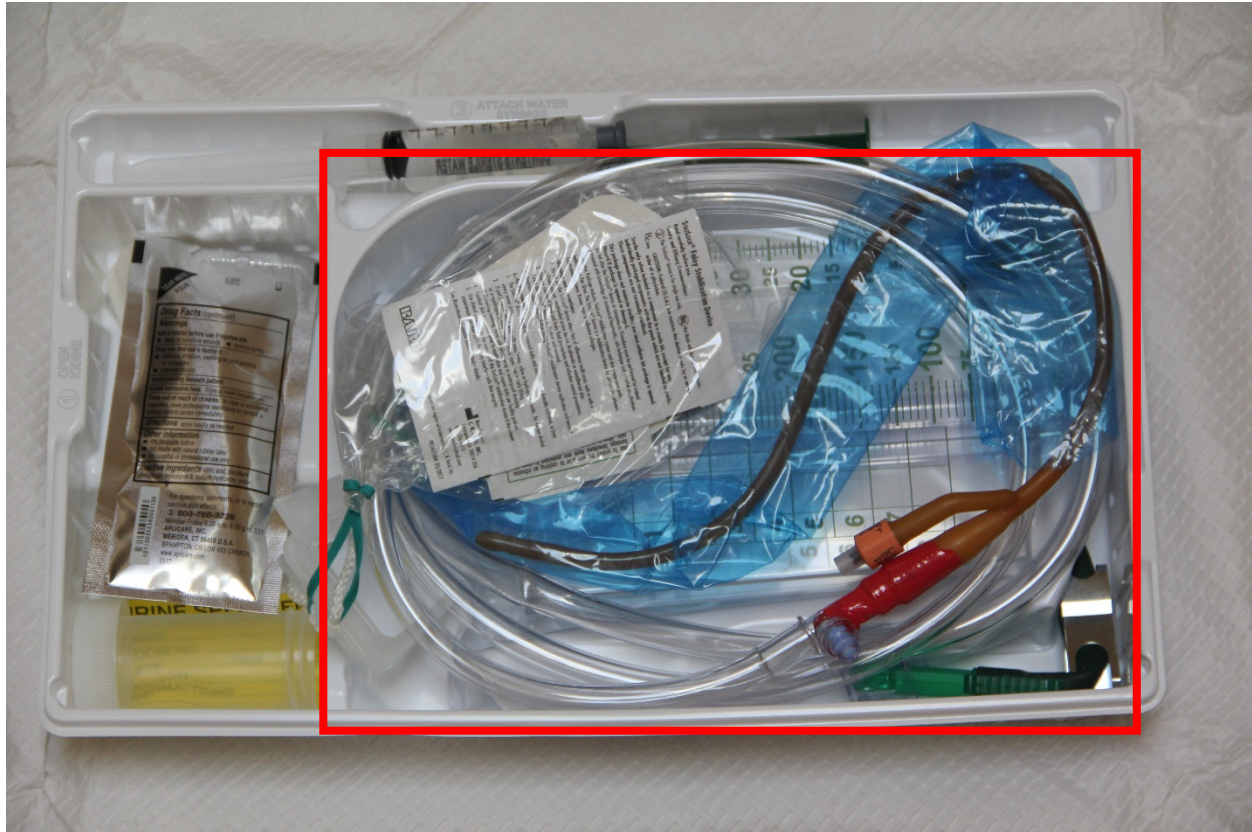


73. The Current SureStep Foley Kit includes a thermally sealed bag disposed about a tray.

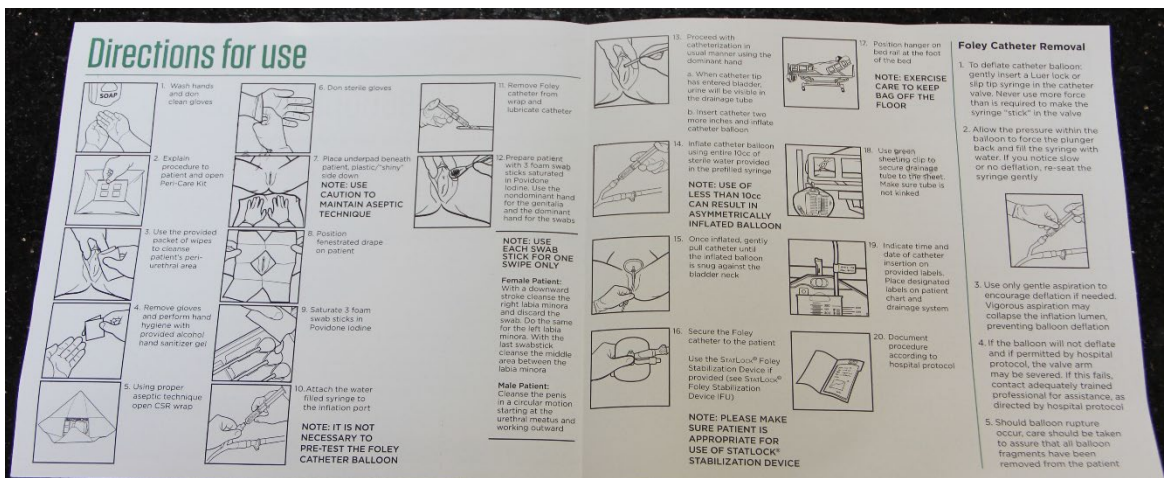


74. Bard intends that healthcare providers open the thermally sealed bag in order to use the Current SureStep Foley Kit.

75. The tray in the Current SureStep Foley Kit contains a catheter assembly.



76. The Current SureStep Foley Kit includes an instruction manual.

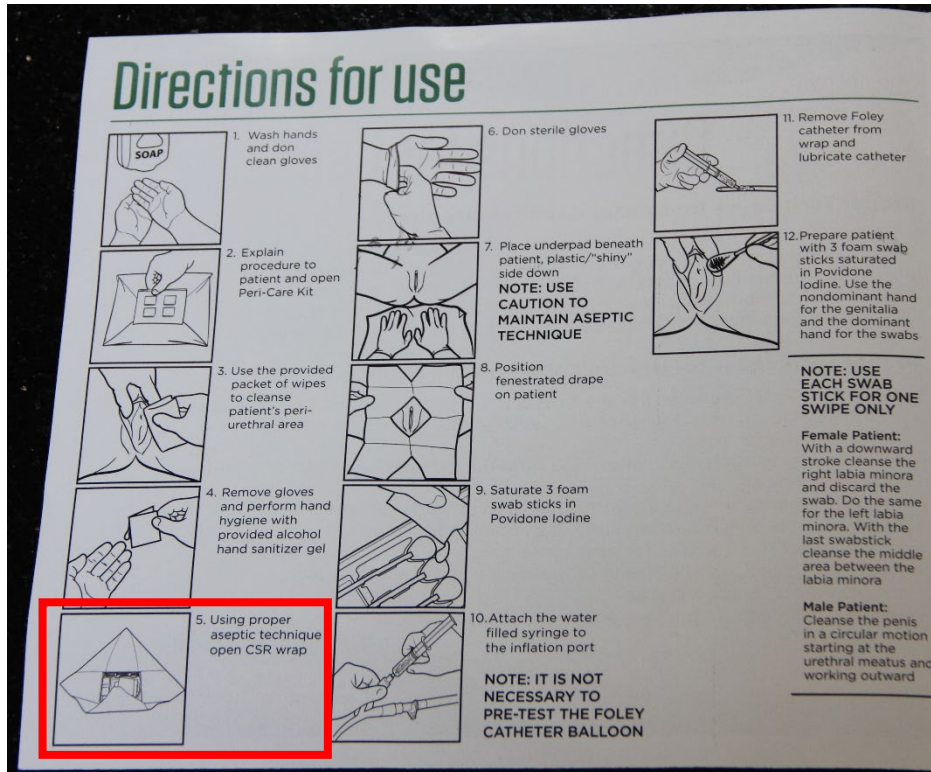


77. Bard intends that healthcare providers access the instruction manual when using the Current SureStep Foley Kit.

78. The tray in the Current SureStep Foley Kit is enclosed in one or more layers of wrap.



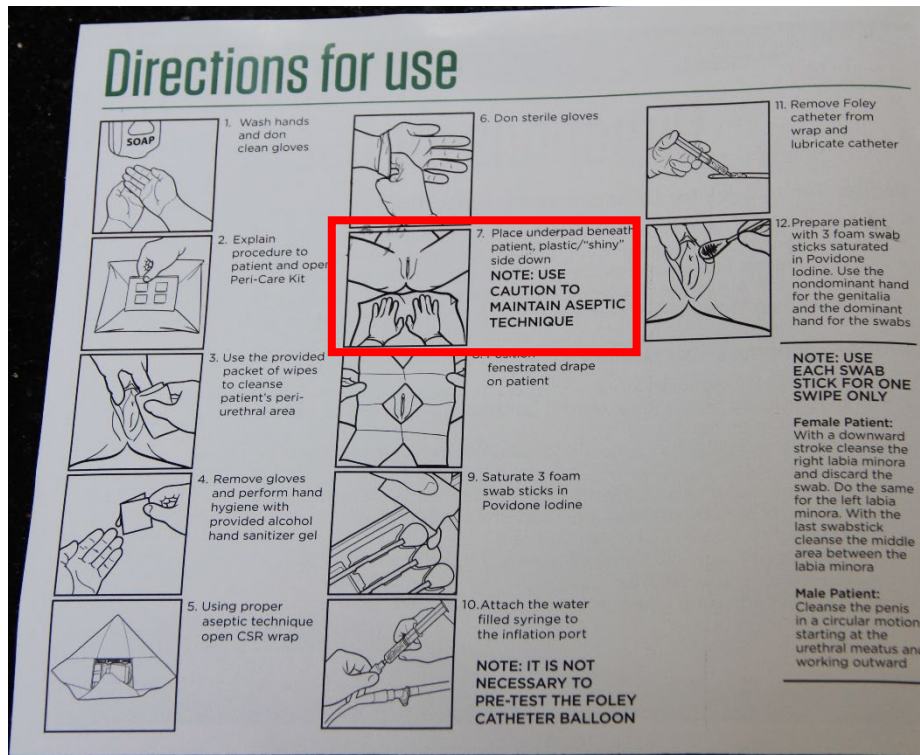
79. Bard intends that healthcare providers unfold the layers of wrap when using the Current SureStep Foley Kit.



80. When the one or more layers of wrap are unfolded by a healthcare provider, an additional layer of wrap and at least a portion of the coiled medical device are revealed.



81. The “Directions for Use” of the Current SureStep Foley Kit instruct clinicians to place the additional layer of wrap beneath the patient.



82. By providing these instructions in connection with the use of the Current SureStep Foley Kit, Bard intends that healthcare providers place a layer of wrap beneath a patient, thereby transforming an area beneath the patient from a non-sterile field to a sterile field.

83. Any healthcare provider who catheterized a patient in the United States in accordance with Bard’s instructions in the “Directions for Use,” using the Current SureStep Foley Kit, directly infringed claim 1 of the ’786 Patent. On

information and belief, based on the millions of Current SureStep Foley Kits sold since early 2016, millions of such acts have taken place.

84. On information and belief, Bard has continued to engage in activities constituting inducement of infringement, notwithstanding its knowledge (or willful blindness thereto) that the activities it was inducing would result in infringement of the '786 Patent. Bard's intentional, knowing inducement to infringe is evident at least from the "Directions for Use" it provides with its Current SureStep Foley Kit.

85. Bard sells and offers for sale the Current SureStep Foley Kit within the United States, including in this district.

86. The Current SureStep Foley Kit constitutes a material part of the invention claimed in the '786 Patent.

87. At least as of early 2016, Bard knew that the Current SureStep Foley Kit is especially made for use in an infringement of Medline's patents, including claim 1 of the '786 Patent.

88. The Current SureStep Foley Kit is not a staple article or commodity of commerce.

89. The Current SureStep Foley Kit has no substantial uses except for use in conjunction with the methods claimed in Medline's Patents, including the '786 Patent.

90. Medline has been irreparably harmed by Bard's infringement of the '786 Patent. Medline's ERASE CAUTI product competes in the market with the Current SureStep Foley Kit. Moreover, Bard's contribution to and inducement of others to infringe the '786 Patent has threatened the value of the '786 Patent because Bard's conduct results in Medline's loss of its lawful patent rights to exclude others from making, using, offering to sell, selling and/or importing the patented inventions.

91. Bard will derive a competitive advantage from using Medline's patented technology without paying compensation for such use. Accordingly, unless and until Bard's continued acts of infringement are enjoined, Medline will suffer further irreparable harm for which there is no adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Medline respectfully requests the following relief:

- A. A judgment holding Bard liable for infringement of the Patent-in-Suit;
- B. A permanent injunction against Bard, its officers, agents, servants, employees, attorneys, parent and subsidiary corporations, assigns and successors in interest, and those persons in active concert or participation with them, enjoining them from continued acts of infringement of the Patent-in-Suit;

- C. Damages to compensate Medline for injuries resulting from Bard's infringement of the Patent-in-Suit, together with pre-judgment and post-judgment interest and costs;
- D. A judgment and order holding that Bard's infringement was willful, malicious, bad faith, deliberate, consciously wrongful, and/or flagrant within the meaning of 35 U.S.C. § 284 and awarding enhanced damages to Medline due to Bard's willful infringement of the Patent-in-Suit;
- E. A judgment holding this Action an exceptional case, and an award to Medline of its attorneys' fees and costs pursuant to 35 U.S.C. § 285; and
- F. Such other relief as the Court deems just and equitable.

JURY DEMAND

Under Rule 38 of the Federal Rules of Civil Procedure, Medline respectfully demands a trial by jury of any issues triable of right by a jury.

Dated: September 25, 2020

Respectfully submitted,

/s/Daniel A. Kent

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