

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

MEDLINE INDUSTRIES, INC.

Plaintiff,

v.

C.R. BARD, INC.

Defendant.

Civil Action No. 1:17-cv-7216

DEMAND FOR JURY TRIAL

**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 350,000 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 2016, Forbes Magazine ranked Medline in the top 50 of largest privately held companies in America. Medline employs more than 15,000 colleagues worldwide, with operations in more than 90 countries.

7. On information and belief, 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. On information and belief, Bard maintains a regular and established place of business in Carol Stream, Illinois.

9. 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, is currently pending before the United States District Court for the Northern District of Illinois, Eastern Division.

10. On March 23, 2016, Medline filed a second action in the Northern District of Illinois asserting that Bard infringes certain claims of U.S. Patent Nos. 8,746,452 and 9,283,352. On April 3, 2017, Medline filed a supplemental complaint adding a claim for infringement of U.S. Patent No. 9,522,753. That litigation, entitled *Medline Industries, Inc. v. C.R. Bard, Inc.*, No. 1:16-cv-03529-SJC-JTG, is currently pending before the United States District Court for the Northern District of Illinois, Eastern Division.

JURISDICTION AND VENUE

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

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

13. Defendant Bard is subject to this Court's personal jurisdiction because it does and has done substantial business in this judicial district, including upon information and belief offering to sell in this judicial district the SureStep Foley Tray System.

14. In addition, on information and belief, Bard directly and/or through its distribution network regularly places the SureStep Foley Tray System in the stream of commerce with the knowledge and/or understanding that such products will be sold and used in Illinois and within this judicial district.

15. Finally, Bard is 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.

16. Venue is proper in this judicial district under 28 U.S.C. § 1400(b) because Bard has committed acts of infringement and has a regular and established place of business in this district.

BACKGROUND

17. A urinary catheter is a thin tube placed in the bladder to drain urine. A Foley catheter is a type of 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 results in catheter-associated urinary tract infection (a.k.a. “CAUTI”).

18. At the time of the inventions 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.

19. 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 length of 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. When bacteria developed, this additional cost increased to at least \$3,800. The Centers for Medicare & Medicaid Services (“CMS”) reported that in 2007, patients with CAUTIs incurred an average cost of \$44,043 per hospital stay.

20. 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

21. 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.

22. In 2009, Medline designed the industry's first one-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: **E**valuate indications; **R**ead instructions; **A**septic technique; **S**ecure catheter; and **E**ducate patient.

23. Before the inventions claimed in the patent-in-suit, the conventional Foley catheter tray had two layers. The base of the tray held the drainage bag and catheter. The upper level of the tray held all of the 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.

24. 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 tray), the clinician can now more easily prepare and use the components within the kit/tray. Additionally, the inventors conceived step-by-step educational instructions to reinforce that the components of the tray are accessible from top to bottom and left to right, in the order in which they are required in the catheterization procedure.

25. Medical facilities that purchased Medline's patent-protected ERASE CAUTI trays experienced immediate positive results. In many instances, the ERASE CAUTI trays helped bring the incidence of CAUTI to zero at the facilities.

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

27. 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.

28. 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.'"

29. Medline practices the claimed inventions. It has sold the following products that are covered by the inventions in the patent-in-suit:

- Latex ERASE CAUTI Foley Catheter Tray
- 100% Silicone ERASE CAUTI Foley Catheter Tray
- Silvertouch 100% Silicone ERASE CAUTI Foley Catheter Tray
- 100% Silicone Temperature Sensing ERASE CAUTI Foley Catheter Tray
- Coude 100% Silicone ERASE CAUTI Foley Catheter Tray
- Coude Latex ERASE CAUTI Tray
- Buddy The Brave ERASE CAUTI Foley Catheter Tray
- Buddy the Brave Temperature Sensing ERASE CAUTI Foley Catheter Tray
- Silicone Total One Layer Foley Catheter Tray
- Silvertouch 100% Silicone Foley Catheter Total 1-Layer Tray
- Silicone-Elastomer Coated Latex ERASE CAUTI Trays

BARD REACTS

30. 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.

31. In 2010, Bard redesigned its Foley catheter tray and began selling a new version, which it called Advance. On information and belief, the Advance tray was designed as a response to Medline's ERASE CAUTI trays and copied certain elements of Medline's ERASE CAUTI system and program. However, the Advance tray maintained the problematic two-layer structure that had defined conventional Foley catheter trays for years.

32. 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 Tray System.

33. On information and belief, the SureStep Foley Tray System was the first single-layer Foley catheter tray developed and/or sold by Bard.

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

35. On information and belief, Bard copied Medline's single-layer design in developing the SureStep Foley Tray System.

THE PATENT-IN-SUIT

36. 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.

37. On August 29, 2017, the United States Patent and Trademark Office duly and legally issued United States Patent No. 9,745,088 (“the ’088 Patent,” a copy of which is attached as Exhibit A hereto), entitled “Catheter Tray, Packaging System, Instruction Insert, and Associated Methods,” to Medline in the names of inventors Jennifer Tomes, Sarah Dickinson, Deborah Adler, Jack Maze, Alberto Savage, Kenneth Chua, Earl Wilson, and John Kutsch.

38. Medline is the owner by assignment of the entire right, title, and interest in the ’088 Patent.

COUNT I: INFRINGEMENT OF THE ’088 PATENT

39. With respect to the ’088 Patent, Bard has been and is now directly infringing at least claim 45 of the ’088 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 SureStep Foley Tray System.

Notice of Infringement

40. On information and belief, before the filing of the suit, Bard was aware of and analyzed Medline’s patents and pending applications, including the ’088 Patent. Bard was placed on notice of Medline’s ’088 Patent infringement claims at least as of the filing of this Complaint.

41. Upon Bard’s gaining knowledge of the ’088 Patent, it was apparent to Bard that the sale of the SureStep Foley Tray System infringes the ’088 Patent.

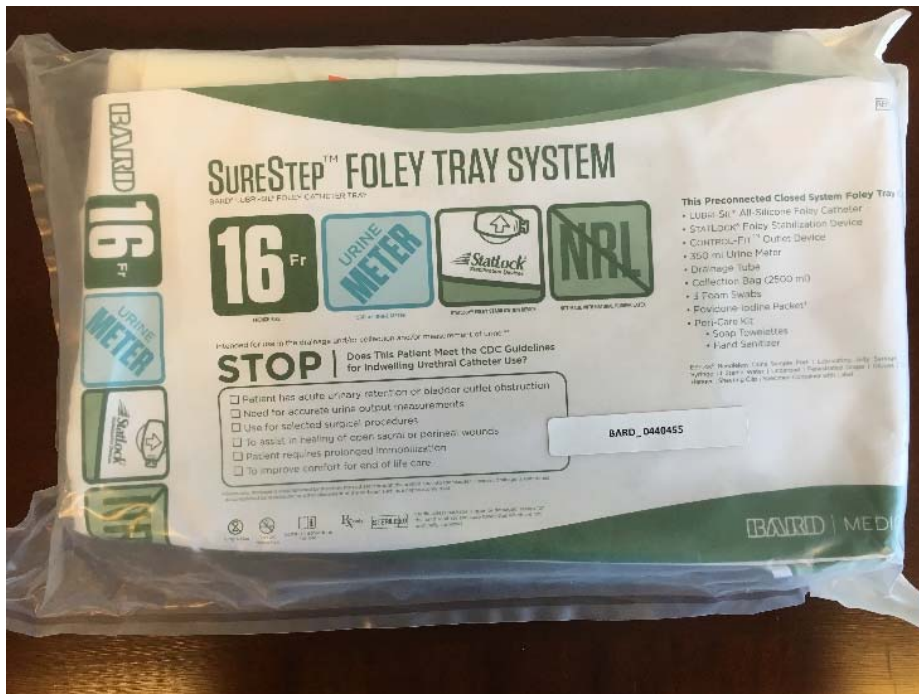
42. On information and belief, upon Bard’s gaining knowledge of the ’088 Patent, Bard has opted to continue its willful, deliberate, and intentional infringement of one or more claims of the ’088 Patent at least by using, selling, importing, and/or offering to sell the SureStep Foley Tray System in reckless disregard of the claims of Medline’s ’088 Patent.

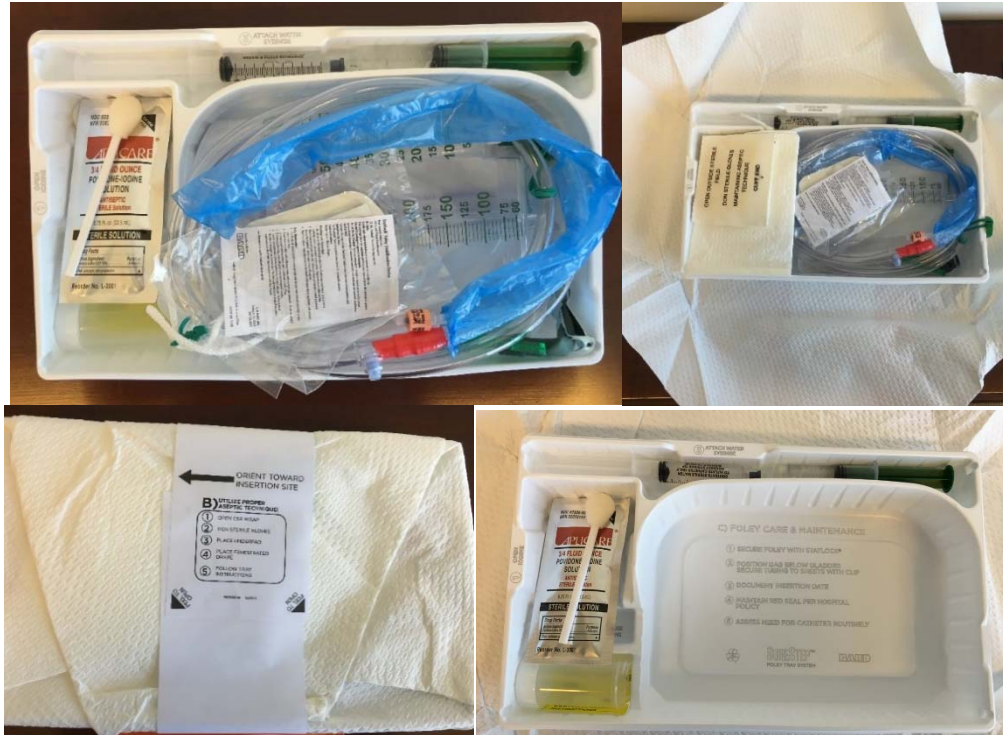
43. Bard has acted despite an objectively high likelihood that its actions constitute an infringement of the '088 Patent. In addition, the risk of infringement was either known by Bard or so obvious to it that the risk should have been known to Bard.

Direct Infringement of the '088 Patent

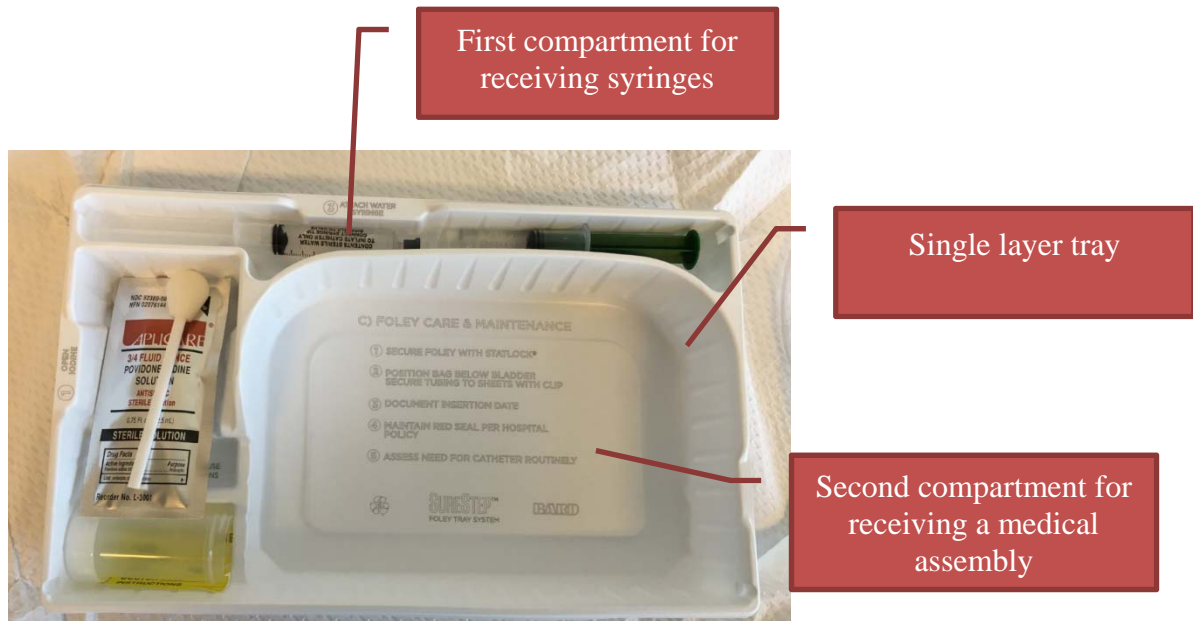
44. Bard has infringed the '088 Patent under 35 U.S.C. § 271 by making, using, selling or offering to sell, or importing into the United States, the SureStep Foley Tray System.

45. For example, Bard has been and is now directly infringing at least claim 45 of the '088 Patent by making and using SureStep Foley Tray System products. An example of the infringing products bearing bates number BARD_0440455 is identified in the pictures below:

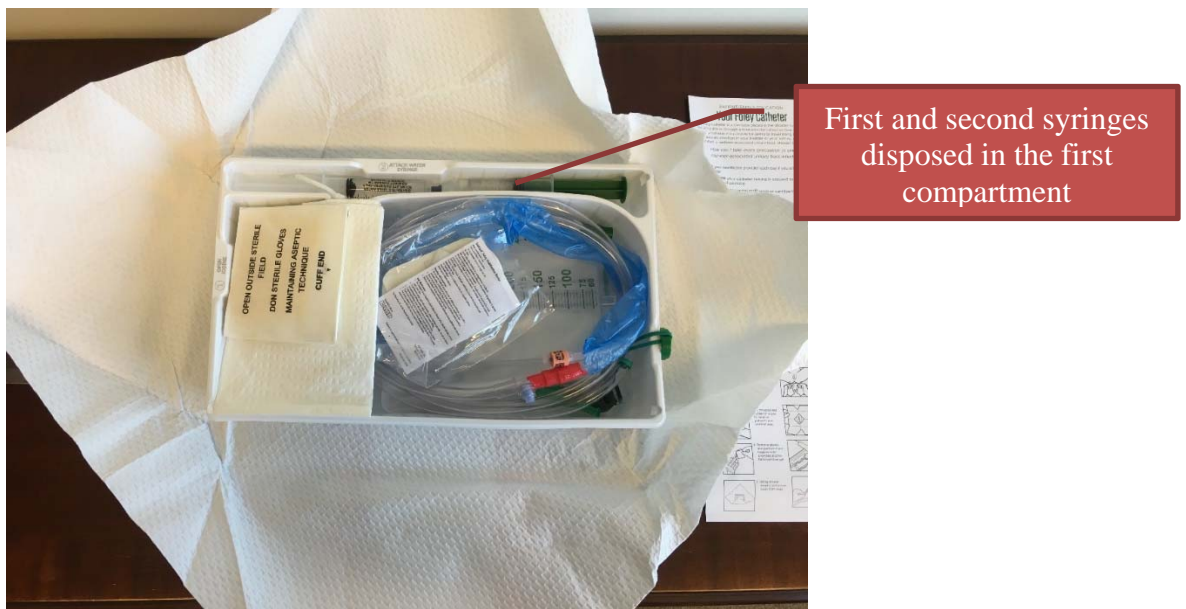




46. Bard infringes at least claim 45 of the '088 Patent by making or using SureStep Foley Tray System products. For example, claim 45 recites: “A medical procedure kit, comprising: a single layer tray having a first compartment for receiving syringes and a second compartment for receiving a medical assembly.” As shown below, the SureStep Foley Tray System is a medical procedure kit (i.e., a Foley catheterization procedure kit), comprising a single layer tray having a first compartment for receiving syringes and a second compartment for receiving a medical assembly.



47. The SureStep Foley Tray System also comprises “a first syringe and a second syringe disposed within the first compartment.” As shown below, the SureStep Foley Tray System includes two syringes disposed within the first compartment of the single layer tray.



48. The “medical assembly” of the SureStep Foley Tray System is “disposed in the second compartment, and the medical assembly comprises a coiled tubing coupled between a fluid drain bag and a Foley catheter.” For example, as shown below the medical assembly comprises a coiled tubing coupled between a fluid drain bag and a Foley catheter



Medical assembly disposed in the second compartment comprising a coiled tubing coupled between a fluid drain bag and a Foley catheter.

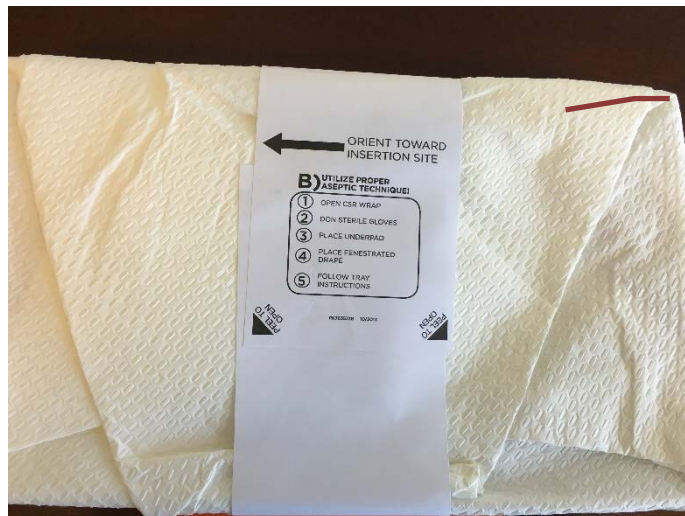


Fluid drain bag coupled to the coiled tubing

49. The SureStep Foley Tray System comprises “at least one layer of wrap material enclosing the single layer tray within one or more folds of the at least one layer of wrap material.” For example, as shown image below, the SureStep Foley Tray System tray is enclosed within one or more folds of wrap material.

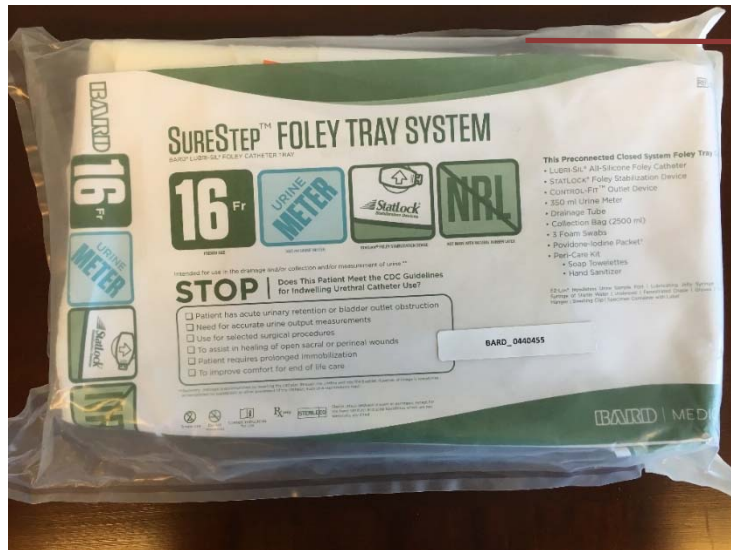


At least one layer of wrap material



The wrap material encloses the single layer tray within one or more folds

50. The SureStep Foley Tray System comprises “an outer packaging disposed about both the single layer tray and the at least one layer of wrap material.” For example, as shown below a plastic outer packaging is disposed about the tray and the wrap.



A clear plastic outer packaging is disposed about the tray and the wrap

51. Because, as shown above, the SureStep Foley Tray System has each element of claim 45 of the '088 Patent, Bard infringes at least claim 45 of the '088 Patent by making, using, selling and/or offering to sell in, or importing into the United States, the SureStep Foley Tray System.

52. Medline has been harmed by Bard's infringement and is entitled to recover damages adequate to compensate it for the injuries complained of herein, including lost profits, but in no event less than a reasonable royalty. Medline is further entitled to an injunction stopping Bard from committing additional acts of infringement, which constitute a willful violation of Medline's rights, and which would subject Medline to irreparable harm.

53. Medline has been and will continue to be irreparably harmed by Bard's infringement of the '088 Patent. Moreover, Bard's infringement has threatened the value of the '088 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.

54. Bard's continuing infringement has and continues to irreparably harm Medline by denying Medline the exclusive enjoyment of the inventions claimed in the Patents-in-Suit.

Specifically, Bard's infringement denies Medline the exclusive right to manufacture, sell, offer to sell, import and market Foley catheter trays covered by the Patents-in-Suit.

55. Bard's infringement irreparably harms Medline by, among other things, eroding the price Medline may receive for its revolutionary Foley catheter trays.

56. Bard's infringement irreparably harms Medline's accumulated goodwill by, among other things, requiring Medline to compete against an infringing product. The competition against Bard's infringing product requires Medline to defend the effectiveness and efficacy of its revolutionary Foley catheter tray to customers Bard is pursuing at the expense of Medline's sales.

57. Furthermore, Bard has disparaged Medline's revolutionary Foley catheter tray covered by the Patents-in-Suit to customers and potential customers of Medline.

58. Bard will derive a competitive advantage from selling, offering to sell, using and/or importing Medline's patented technology without paying compensation for such sales, offers to sell, use and/or importation. 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 '088 patent;
- 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 '088 patent;
- C. Damages to compensate Medline for injuries resulting from Bard's infringement of the '088 patent, together with pre-judgment and post-judgment interest;
- D. Pursuant to 35 U.S.C. § 284, a judgment trebling damages awarded to Medline due to Bard's willful infringement of the '088 patent;
- 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.

Dated: October 5, 2017

Respectfully submitted,

/s/ Allen E. Hoover 06216256

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