

Advances in Patient Safety

Contamination studies point to a new strategy in the war against hospital infections

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The luer tip of a standard syringe is exposed to the risk of transmission of pathogens that can lead to hospital-acquired infections. To address this problem, a new patient safety syringe has recently been developed. Two studies were conducted by an independent laboratory to determine whether the new device reduces the risk of contamination, compared to a standard syringe.

Background

Each year there are about 1.7 million healthcare-associated infections in U.S. hospitals, and they result in approximately 99,000 deaths, according to the Centers for Disease Control and Prevention (CDC).¹ Methicillin-resistant *Staphylococcus aureus* (MRSA) infections and other antibiotic-resistant “super bugs” increasingly over the past few years have become a major concern in hospitals throughout the world. MRSA “is a major public health problem primarily related to health care.”² About 14 percent, or 238,000 of the 1.7 million annual infections in U.S. hospitals, are bloodstream infections.³ Worse yet, these numbers are growing at an alarming rate.

Besides the high toll in terms of lives lost and illnesses suffered, there is also the economic cost. The monetary cost in hospitals in the United States amounts to almost \$5 billion annually. Beginning on October 1, 2008, CMS (Medicare) will no longer reimburse hospitals

for eight hospital-acquired conditions, including vascular catheter-associated infections.⁴ “Private insurers usually base their payments on Medicare’s fee schedule.”⁵

Hospitals have responded to the problem with a variety of approaches including handwashing, training, etc. However, until now there have been no design or engineering controls available to prevent the risk of contact contamination associated with the luer end of a syringe. The luer tip of a standard syringe is exposed to the risk of contamination by pathogens that could be transmitted to patients via intra venous (IV) access valves and IV fluids, both of which can increase patients’ risk for bloodstream infections.

Standard syringes with luer lock tips have a threaded collar surrounding the conical luer tip. The exposure of the luer tip allows for contact contamination of the tip during medication preparation, transporting medication to the patient areas, and handling prior to injection or infusion. Due to the proliferation of needleless IV systems in the United States, many intravenous injections are performed using luer tip syringes in conjunction with luer-activated valve (LAV) access devices.

In an effort to avert contamination during these intravenous injections, it is common practice to swab the surface of LAV devices prior to access, and to swab the vial stoppers prior to medication preparation. However, the luer tip of a standard syringe is exposed to the risk of contact contamination by healthcare personnel, as well as through contact with multiple surfaces (e.g., countertops in medication and patient rooms, over-the-bed tables in patient rooms, bedding in patient rooms, and healthcare personnel’s clothing). Since the luer tip directly interfaces with the access port,



contamination of the luer tip has the potential for contaminating the access port and infusate, which increases the patient’s risk of nosocomial infections, such as bloodstream infections.

Patient Safe™ syringes (a newly introduced product from Retractable Technologies Inc.) are designed to connect to luer connection devices, such as standard hypodermic needles or vial access devices for the aspiration of fluids and medication, as well as LAV devices for the injection of fluids and medication. The threaded collar surrounds and extends beyond the luer tip, protecting it from contact contamination. A unique “petal” design allows the luer guard to accommodate a variety of differently shaped interfacing devices, such as hypodermic needles with manually activated safety features. This extended petal design also serves as a guide to aid the user in aligning the syringe with the interfacing device, preventing inadvertent contamination.



The Patient Safe™ syringe’s unique luer guard protects the luer tip against contact contamination, while the petal design allows the collar to expand if needed.

Studies were conducted at an independent commercial laboratory to determine if Patient Safe syringes or currently marketed standard luer lock syringes prevent contact contamination of the syringe luer tip and subsequent contamination of liquids administered to patients either by direct injection or via an intravenous access system. Two studies were conducted, with the following objectives:

1. To test the Patient Safe syringe and the standard luer lock syringe to quantify and compare the risk of syringe luer tip contamination transfer to the liquid drawn into the syringe.
2. To test the Patient Safe syringe and the standard luer lock syringe in order to quantify and compare the risk of syringe luer tip contamination transfer to LAV devices and infusate.

Study 1 – Test of contamination transfer to liquid drawn into syringes

Test methods:

- ▶ Agar plates were inoculated with *Geobacillus stearothermophilus* and incubated for 24 hours.
- ▶ The luer end of Patient Safe syringes and standard syringes were placed on the surface of the agar.
- ▶ Using aseptic technique, sterile hypodermic needles were attached to the syringes.
- ▶ Each syringe was filled with 2mL of sterile saline taken from separate vials (one vial per syringe).
- ▶ The contents were expelled through the needle into a sterile container.
- ▶ The contents of each sample were incubated for at least than 48 hours and the number of *Geobacillus stearothermophilus* colonies was counted.

Results:

Table 1. Colonies of *Geobacillus stearothermophilus* counted

Sample No.	Patient Safe Syringes	Standard Syringes
1	0	307
2	0	147
3	0	298
4	0	310
5	0	190
6	0	238
7	0	174
8	0	180
9	0	357
10	0	309
Negative Controls	0	0
Positive Control One	3.3 x 10 ³	3.6 x 10 ³
Positive Control Two	2.4 x 10 ³	3.1 x 10 ³
Positive Control Mean	2.9 x 10 ³	3.4 x 10 ³

The results demonstrated that the Patient Safe syringes protected the fluid pathway and subsequently prevented contamination of the fluid drawn into the syringe. The study demonstrated that the Patient Safe syringe showed no contamination of the syringe contents in any instance (0 percent), while the standard syringe demonstrated contamination of the syringe contents in every instance (100 percent).



Patient Safe™ syringes are compatible with luer-activated valve access devices, such as the ICU Medical CLAVE® connector.

Study 2—Test of contamination transfer to LAV and infusate

Test methods:

- ▶ Agar plates were inoculated with *Geobacillus stearothermophilus* and incubated for 24 hours.
- ▶ Using aseptic technique, sterile Patient Safe syringes and standard syringes were opened and attached to sterile 22G x 1-inch standard hypodermic needles.
- ▶ Each syringe was filled with 2mL sterile saline.
- ▶ The needles were removed.
- ▶ The luer ends of Patient Safe syringes and standard syringes were placed on the surface of the agar.
- ▶ The syringes were attached to separate valves (each opened using aseptic technique and swabbed with alcohol) and the contents expelled through the valve into a sterile container.
- ▶ The contents of each sample were incubated for at least 48 hours and the number of *Geobacillus stearothermophilus* colonies was counted.

Results:

The results of Study 2 demonstrated that the Patient Safe syringe protects the fluid pathway, and subsequently the patient, from contamination when connecting the syringe to an access valve and pushing liquid through the

valve. The study demonstrated that for each of the three brand of valves tested, the Patient Safe syringe showed no contamination beyond the valve in any instance (0 percent), while the standard syringe demonstrated contamination beyond the valve in every instance (100 percent).

Table 2. Colonies of *Geobacillus stearothermophilus* counted

No.	Patient Safe w/ Valve A	Patient Safe w/ Valve B	Patient Safe w/ Valve C	Standard w/ Valve A	Standard w/ Valve B	Standard w/ Valve C
1	0	0	0	186	201	180
2	0	0	0	135	320	79
3	0	0	0	173	301	202
4	0	0	0	192	241	103
5	0	0	0	82	208	122
6	0	0	0	161	113	152
7	0	0	0	211	270	102
8	0	0	0	205	215	123
9	0	0	0	174	264	94
10	0	0	0	195	173	103
Neg. Control	0	0	0	0	0	0
Pos. Control	5.0 x 10 ³	3.1 x 10 ³	3.8 x 10 ³	3.4 x 10 ³	3.5 x 10 ³	4.1 x 10 ³

Conclusion

These studies show that the Patient Safe syringe prevents contact contamination of the syringe luer tip and subsequent contamination of liquids administered to patients either by direct injection or via an intravenous access system, whereas currently marketed standard luer lock syringes do not. †

References

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3. "Estimates of Healthcare-Associated Infections."
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