IV Accessories

SwabCap® Disinfection Cap

Clinical Evidence Summary

B BRAUN
SHARING EXPERTISE

Content Overview
SwabCap® – Disinfection Cap

Laboratory Publication

Internal Laboratory Tests

Features & Benefits

1. Disinfection of Needleless Connector Hubs: Clinical Evidence Systematic Review

Moureau NL, Flynn J. Nurs Res Pract. 2015; Vol. 2015, Article ID: 796762. doi: 10.1155/2015/796762.

1.1 Background

Needleless connectors (NC) are used on virtually all intravascular devices, providing an easy access point for infusion connection. Colonization of NC is considered the cause of 50 % of postinsertion catheter-related infections. Breaks in aseptic technique, from failure to disinfect, result in contamination and subsequent biofilm formation within NC and catheters increasing the potential for infection of central and peripheral catheters.

1.2 Method

This systematic review evaluated 140 studies and 34 abstracts on NC disinfection practices, the impact of hub contamination on infection, and measures of education and compliance.

1.3 Results

The greatest risk for contamination of the catheter after insertion is the NC with 33 - 45 % contaminated, and compliance with disinfection as low as 10 %. The optimal technique or disinfection time has not been identified, although scrubbing with 70 % alcohol for 5 - 60 seconds is recommended.

Studies have reported statistically significant results in infection reduction when passive alcohol disinfection caps are used (48 - 86 % reduction).

1.4 Conclusion

It is critical for healthcare facilities and clinicians to take responsibility for compliance with basic principles of asepsis compliance, to involve frontline staff in strategies, to facilitate education that promotes understanding of the consequences of failure, and to comply with the standard of care for hub disinfection.

1.5 Key Findings

Rather than creating devices such as the ultraviolet C port to eradicate contamination within the hub, the goal should be to eliminate surface pathogens before entering the NC or catheter. Passive disinfection caps reduce guess work, provide clinicians with a point of use solution, and reduce contamination.

2. Use of Disinfection Cap to Reduce Central-Line-Associated Bloodstream Infection and Blood Culture Contamination Among Hematology-Oncology Patients

Kamboj M, Blair R, Bell N, Son C, Huang YT, Dowling M, Lipitz-Snyderman A, Eagan J, Sepkowitz K. Infect Control Hosp Epidemiol. 2015 Dec;36(12):1401-8. doi: 10.1017/ice.2015.219.

2.1 Objective

In this study, we examined the impact of routine use of a passive disinfection cap (SwabCap®, ICU Medical Inc., San Clemente, CA) for catheter hub decontamination in hematology–oncology patients.

2.2 Setting

A tertiary care cancer center in New York City.

2.3 Methods

In this multiphase prospective study, we used 2 preintervention phases (P1 and P2) to establish surveillance and baseline rates followed by sequential introduction of disinfection caps on high-risk units (HRUs: hematologic malignancy wards, hematopoietic stem cell transplant units and intensive care units) (P3) and general oncology units (P4). Unit-specific and hospital-wide hospital-acquired central-line–associated bloodstream infection (HA-CLABSI) rates and blood culture contamination (BCC) with coagulase negative staphylococci (CONS) were measured.

2.4 Conclusion

Implementation of a passive disinfection cap resulted in a 34 % decrease in hospital-wide HA-CLABSI rates (combined P1 and P2 baseline rate of 2.66 – 1.75 per 1,000 catheter days at the end of the study period). This reduction occurred only among high-risk patients and not among general oncology patients. In addition, the use of the passive disinfection cap resulted in decreases of 63 % (HRUs) and 51 % (general oncology units) in blood culture contamination, with an estimated reduction of 242 BCCs with CONS.

The financial implications have been evaluated by calculating the annualized numbers of prevented HA-CLABSIs and BCCs by comparing the expected and observed infections or contaminations. These estimates were then translated into cost savings using averages derived from published upper and lower estimates of the direct attributable medical cost of HA-CLABSI and BCC.

2.5 Key Findings

Routine use of disinfection caps is associated with decreased HA-CLABSI rates among high-risk hematology oncology patients and a reduction in blood culture contamination among all oncology patients.

3. Reducing Bloodstream Infection Risk in Central and Peripheral Intravenous Lines: Initial Data on Passive Intravenous Connector Disinfection

DeVries M, Mancos P S, Valentine M J. Journal of the Association for Vascular Access. 2014 Jun;19(2):87-93. doi: 10.1016/j.java.2014.02.002.

3.1 Background

Although few facilities focus on it, bloodstream infection (BSI) risk from peripheral intravenous catheters (PIVs) may exceed central line-related risk. Over a 6-year period, Methodist Hospitals substantially reduced BSIs in patients with central lines but not in patients with PIVs. A practice audit revealed deficiencies in manual disinfection of intravenous connectors, thereby increasing BSI risk. Methodist thus sought anengineered approach to hub disinfection that would compensate for variations in scrubbing technique.

3.2 Methods

The author's institution involved bedside nurses in choosing new hub disinfection technology. They selected 2 devices to trial: a disinfection cap that passively disinfects hubs with isopropyl alcohol and a device that friction-scrubs with isopropyl alcohol. After trying both, nurses selected the cap for use in the facility's 3 intensive care units.

After no BSIs occurred during a 3-month span, we implemented the cap throughout the hospital for use on central venous catheters; peripherally inserted central catheters; and peripheral lines, including tubing and Y-sites.

3.3 Results

Comparing the postintervention period (December 2011-August 2013) to the preintervention span (September 2009-May 2011), the BSI rate dropped 43 % for PIVs, 50 % for central lines, and 45 % overall (PIVs + central lines). The central line and overall results are statistically significant. The PIV BSI rate drop is attributable to cap use alone because the cap was the only new intervention during the postimplementation period. The other infection reductions appear to be at least partly due to cap use.

3.4 Key Findings

The author's institution achieved substantial BSI reductions, some statistically significant, by applying a disinfection cap to both PIVs and central lines.

4. Continuous passive disinfection of catheter hubs prevents contamination and bloodstream infection

Wright MO, Tropp J, Schora DM, Dillon-Grant M, Peterson K, Boehm S, Robicsek A, Peterson LR. Am J Infect Control. 2013 Jan;41(1):33-8. doi: 10.1016/j.ajic.2012.05.030.

4.1 Background

Catheter hub decontamination requires a thorough scrub and compliance varies. This study evaluates the effectiveness of a disinfection cap with 70 % alcohol in preventing contamination/infection.

4.2 Methods

A 3-phased, multifacility, quasi-experimental study of adult patients with central lines divided into P1 (baseline), when the standard scrub was used; P2, when the cap was used on all central lines; and P3, when standard disinfection was reinstituted. House-wide central-line associated bloodstream infection (CLABSI) rates are reported with catheter-associated urinary tract infections (CAUTI) as a control measure. Adults with peripherally inserted central catheters inserted during hospitalization having 5+ consecutive line-days gave consent and were enrolled, and 1.5 mL of blood was withdrawn from each lumen not in use and quantitatively cultured.

4.3 Results

Contamination was 12.7 % (32/252) during P1; 5.5 % (20/364) in P2 (P = .002), and 12.0 % (22/183; P = 0.88 vs P1 and P = .01 vs P2) in P3 (P = .001 vs P2).

The median colony-forming units per milliliter was 4 for P1, 1 for P2 (P = .009), and 2 for P3 (P = .05 vs P2).

CLABSI rates declined from 1.43 per 1,000 line-days (16/11,154) to 0.69 (13/18,972) in P2 (P = .04) and increased to 1.31 (7/5,354) in P3.

CAUTI rates remained stable between P1 and P2 (1.42 and 1.41, respectively, P = .90) but declined in P3 (1.04, P = .03 vs P1 and P2).

4.4 Key Findings

Disinfecting caps reduce line contamination, organism density, and CLABSIs.

5. Prospective Observational Study on Central Line–Associated Bloodstream Infections and Central Venous Catheter occlusions using a Negative Displacement Connector with an Alcohol Disinfecting Cap

Patel PA, Boehm S, Zhou Y, Peterson KE, Grayes A, Peterson LR. Am J Infect Control. 2016 Aug;45(2):115-120. doi: 10.1016/j.ajic.2016.06.013.

5.1 Background

Major complications of central venous catheter (CVC) use include bloodstream infection and occlusion. We performed a prospective, observational study to determine the rate of central line–associated bloodstream infection (CLABSI) and CVC occlusion using a negative displacement connector with an alcohol disinfecting cap.

5.2 Methods

Patients were followed from the time of CVC insertion through 2 days after removal, at the time of hospital discharge if there was no documentation of removal, or 90 days after the insertion of the CVC if it was not removed. CLABSI was defined using National Healthcare Safety Network criteria. Data for evidence of lumen occlusions were extracted from the electronic health record. Direct observations were performed to assess adherence to hospital policy regarding CVC insertion practice.

5.3 Results

A total of 2,512 catheters from 2,264 patients were enrolled for this study.

There were 21 CLABSIs (0.84 %; 95 % confidence interval [CI], 0.48 %-1.19 %; 0.62 per 1,000 line days) and 378 occlusions (15.05 %; 95 % CI, 13.65 %-16.45 %; 11.23 per 1,000 line days).

Eighty-five direct observations demonstrated insertion protocol adherence in 881 of 925 (95.24 %; 95 % CI, 93.87 %-96.61 %) measured criteria.

5.4 Key Findings

The utilization of a negative displacement connector with an alcohol cap in a standardized protocol for placing lines results in low infection rates. It was also established that the occlusion rate is > 15-fold the CLABSI rate.

6. Microbial Barrier Performance Study of SwabCap® on Needlefree Connectors

Report of a study commissioned by ICU Medical, Inc. and conducted by Ethox International

6.1 Purpose

The purpose of this study was to evaluate the microbial barrier performance of SwabCap® on needlefree connectors and their ability to maintain a disinfected surface on connectors seven days after application, if not removed.

6.2 Methods

A protocol was developed and executed by Ethox International™ comparing the potential for aerosol microbial contamination of needlefree connectors covered with a SwabCap® and needlefree connectors that were not covered with a SwabCap® across 15 different needlefree connector types. Twelve needlefree connectors from each of the 15 needlefree connector types were used for positive controls (uncovered needlefree connectors, exposed, and recovered). One SwabCap® was placed on each needlefree connector.

The caps were then over-torqued twice to provide the opportunity for the worst case fit of the SwabCap® onto each needlefree connector and further limit the barrier properties of the device. Capped needlefree connectors were left at ambient temperature (20 - 25 °C) for 7 days to simulate the effects of a 7-day period of use including any drying out of the disinfectant or relaxing of the cap material which might affect the barrier properties of the device.

6.3 Aerosol Preparation

Nine (9) mL of saline test solution (saline TS) was inoculated with an appropriate amount of a Bacillus atrophaeus (Ba) spore suspension to achieve final concentration of approximately 1.0x107 colony forming units (cfu) / mL. Serial dilutions were made and plated with Tryptic Soy Agar (TSA) to determine the actual concentration. Plates were incubated at 30 - 35 °C for 18 - 48 hours, then counted using colony counter and counts recorded.

6.4 Microbial Barrier Performance Procedure

Capped (test) and uncapped (control) needlefree connectors were suspended in the aerosol chamber so they did not touch each other. Six (6) fallout plates containing TSA and four sterile gauze sponges (4 sq. in.) were placed in the chamber to serve as positive controls. Five (5) mL of inoculated saline TS was pipetted into a DeVilbiss Nebulizer attached to the chamber and a regulated nitrogen tank. The inoculated buffer was aerosolized into the chamber. After aerosolization the fans were allowed to run for 30 - 35 minutes, and then turned off. The chamber was allowed to remain stationary for a minimum of 30 minutes. Each sample was removed from the chamber. The exterior of the capped needlefree connectors were decontaminated with UV light for 5 minutes.

Caps from the test samples were removed and each test was recovered by swabbing with a sterile cotton swab pre-wetted with sterile phosphate buffer with 0.1 % polysorbate 80. The swab was then transferred to 10 mL of sterile phosphate buffer with 0.1 % polysorbate 80, vortexed, and either 0.1 or 1 mL of the buffer was plated to obtain a countable range. Test and control plates were incubated at 30 - 35 °C for 18 - 48 hours. After incubation, the plates were counted and counts recorded. The gauze sponges were removed from the aerosol challenge chamber and extracted in 50 mL volumes of phosphate buffer with 0.1% polysorbate 80 for 30 - 35 minutes. After extraction, 0.1 and 1 mL aliquots were plated in duplicate with TSA, then plates were incubated at 30 - 35 °C for 18 - 48 hours.

After incubation, the plates were averaged and multiplied by 50 or 500 to determine the total number of organisms on the gauze swatch. The value was divided by 4 to determine the average challenge delivered to each package, reported in cfu / in2. Fallout plates were removed from the chamber and incubated at 30 - 35 °C for 18 - 48 hours. Due to high fallout, three, one cm2 sections of each plate were counted and recorded. The average of those three sections represents the average fallout in cfu / cm^2 of each plate. The fallout on each plate was averaged to represent the average challenge (cfu / cm^2) delivered in the chamber.

6.3 Results

The average recovered organism count for the uncapped needlefree connectors ranged from 1.1 x 103 to 9.3 x 102 cfu's. The average recovered organism count for the SwabCap®-capped needlefree connectors ranged from 0.0 to 1.2 cfu's.
On all needlefree connectors tested, the SwabCap® provided at least a 2.77 log difference in the amount of aerosolized organisms allowed to contaminate the top surface and threads of the connector.

4.4 Key Findings

Based on results of the microbial barrier performance testing above, it was determined that the SwabCap® disinfecting cap provides an effective microbial barrier to the top surface of all luer access needlefree connectors tested after seven days and is an appropriate way to maintain an antiseptic condition on the surface of the needlefree connector. Per the device's FDA 510(k) clearance, the SwabCap® disinfecting cap help prevent the transfer of environmental contaminants, including bacterial and airborne contaminants into the system.

7. Thirty-Second Disinfection Study for SwabCap®

Report of a study commissioned by ICU Medical, Inc. and conducted by Toxikon

7.1 Objective

A protocol was developed and executed by Toxikon (Toxikon Corporation, Bedford, MA), a leading preclinical contract research organization (CRO) to characterize the antimicrobial efficacy of the SwabCap® against four strains of bacteria: Pseudomonas aeruginosa, Staphylococcus aureus, Enterobacter cloacae, and Candida albicans.

7.2 Overview

For each organism, 10 test articles were utilized. A total of three needlefree connectors were inoculated and not subjected to SwabCap® treatment to establish a comparative, positive control baseline. A single SwabCap® with a needlefree connector was not challenged but subjected to the same recovery procedure and used as a negative control. The septum of each needlefree connector was challenged, and the SwabCap® were then applied. The test system was incubated under ambient conditions for a period of 30 seconds, and surviving organisms were determined.

7.3 Test Organism Preparation

Individual cultures of P. aeruginosa, S. aureus, and E. cloacae were grown in Trypticase Soy Broth (TSB) and incubated aerobically for 43 hours and 30 minutes at 30 – 35 °C.

C. albicans was grown in TSB and incubated aerobically for 71 hours at 20 – 25 °C. Saturated cultures were standardized to ≥ 107 CFU / mL and used for the microbial challenge. Inoculation verification of the above suspension was performed in duplicate to confirm the culture concentrations. The bacterial plates were incubated aerobically at 30 – 35 °C for five days. Upon completion, the plates were enumerated for colony count determination. The number of microorganisms deposited on each test article was converted for log10 reduction determination.

7.4 Test Procedure

For each organism, a 10 µL droplet of ≥ 107 CFU / mL (≥ 105 CFU / sample) was deposited on the septum of the needlefree connectors. A SwabCap® was secured to 10 samples (for each strain and time point). During SwabCap® application to the needlefree connector, the cap was turned until snug on the needlefree connector. Positive control samples (needlefree connectors) were challenged and recovered after 30 seconds. Samples were allowed to incubate under ambient conditions for 30 seconds within a laminar flow hood. During incubation, samples were maintained in the upright position.

Table 1: Study Matrix

Sample	Needlefree Connector Challenge	SwabCap® Application	Number of Samples / Conditions			
			P. aeruginosa	S. aureus	E. cloacae	C. albicans
Positive	+	-	3	3	3	3
Test	+	+	10	10	10	10
Negative	-	+	1	1	1	1

"+" indicates process inclusion, "-" indicates step omitted.

7.5 Description of Test Organism Quantification

Upon completion of the ambient incubation period, the number of surviving microorganisms from each test article was determined by separating the SwabCap® from the needlefree connectors and subjecting the connectors to two fluid flushes, each of a 10 mL volume (total flush volume = 20 mL). Serial dilution, spread plating, and membrane filtration determined the number of surviving organisms. Enumeration was performed on Trypticase Soy Agar (TSA) plates after incubation at 30 – 35 °C for up to five days.

7.6 Overview

Data in Table 2 below demonstrate antimicrobial efficacy against all strains after 30 seconds of exposure time, and the average log10 reduction to control for all strains was ≥ 4. These data results satisfy the acceptance criteria for antimicrobial efficacy of the SwabCap® when applied to needlefree connectors contaminated with P. aeruginosa, S. aureus, E. cloacae, and C. albicans.

Table 2: Antimicrobial efficacy

Challenge Strain	Log_{10} Reducation Challenge		Average Result
	Acceptance criteria	Observed	
P. aeruginosa	≥ 4.0	5.2	Pass
S. aureus	≥ 4.0	5.3	Pass
E. cloacae	≥ 4.0	4.9	Pass
C. albicans	≥ 4.0	4.3	Pass

*Observed result value is the average log10 Reduction to Control.

4.4 Key Findings

All test samples exceeded the minimum 4-log reduction after 30 seconds.

SwabCap® – Features & Benefits

Disinfection Cap for Needleless Connectors

SwabCap® Disinfection Cap

Disinfection Cap with 70 % Isopropyl Alcohol (IPA)

When twisting the sterile SwabCap® onto the needleless connector, the sponge gets compressed, bathing the valve's top and threads in 70 % IPA. Within 30 seconds the cap achieves a near-complete kill of pathogens. The cap remains in place until the next catheter access to protect the needleless connector from touch and airborne contamination. After cap removal the valve is ready for access. Additional disinfection is not necessary!

Designed to enhance compliance within the hospital

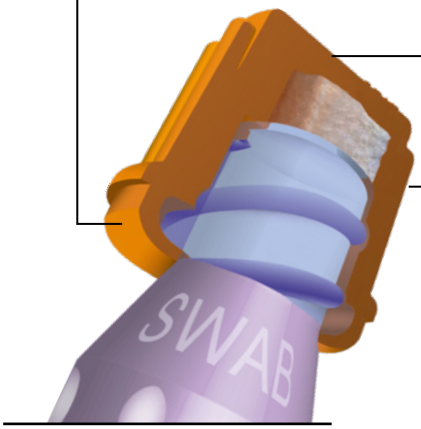
Needleless connector disinfection compliance is visual and measurable.

SwabCap® Disinfection Cap

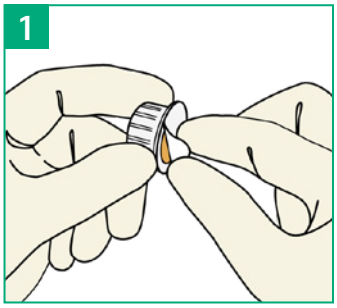
Disinfectant:	70 % IPA
Disinfection time:	30 seconds
Usage time:	7 days if not removed
Not made with Latex or DEHP:	✓

Thread cover seal
Alcohol stays in and keeps contaminants out.

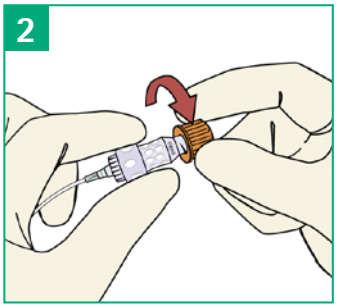
70 % IPA
Bathes both threads and top of connector in IPA



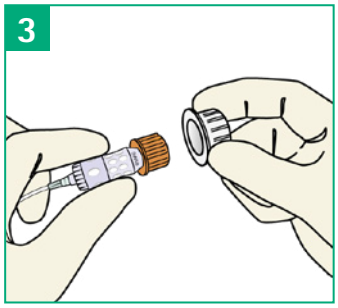
Colored Cap
For visual compliance confirmation



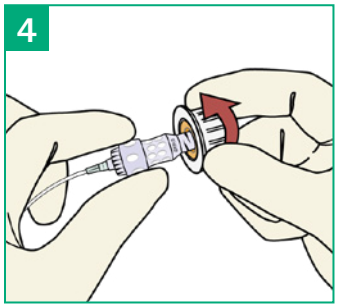
Peel
Remove protect cover.



Push and twist
Push and twist SwabCap® in a clockwise direction onto the needleless connector.



Protect
Pull the white plastic holder off.



Remove
Twist SwabCap® counter-clockwise away from the needleless connector.

For more information, please scan the QR-code or visit:
www.bbraun.com/en/products/b1/swabcap

B. Braun Melsungen AG | Hospital Care | 34209 Melsungen | Germany
Tel. +49 5661 71-0 | www.bbraun.com

Date of last revision: 05.2023