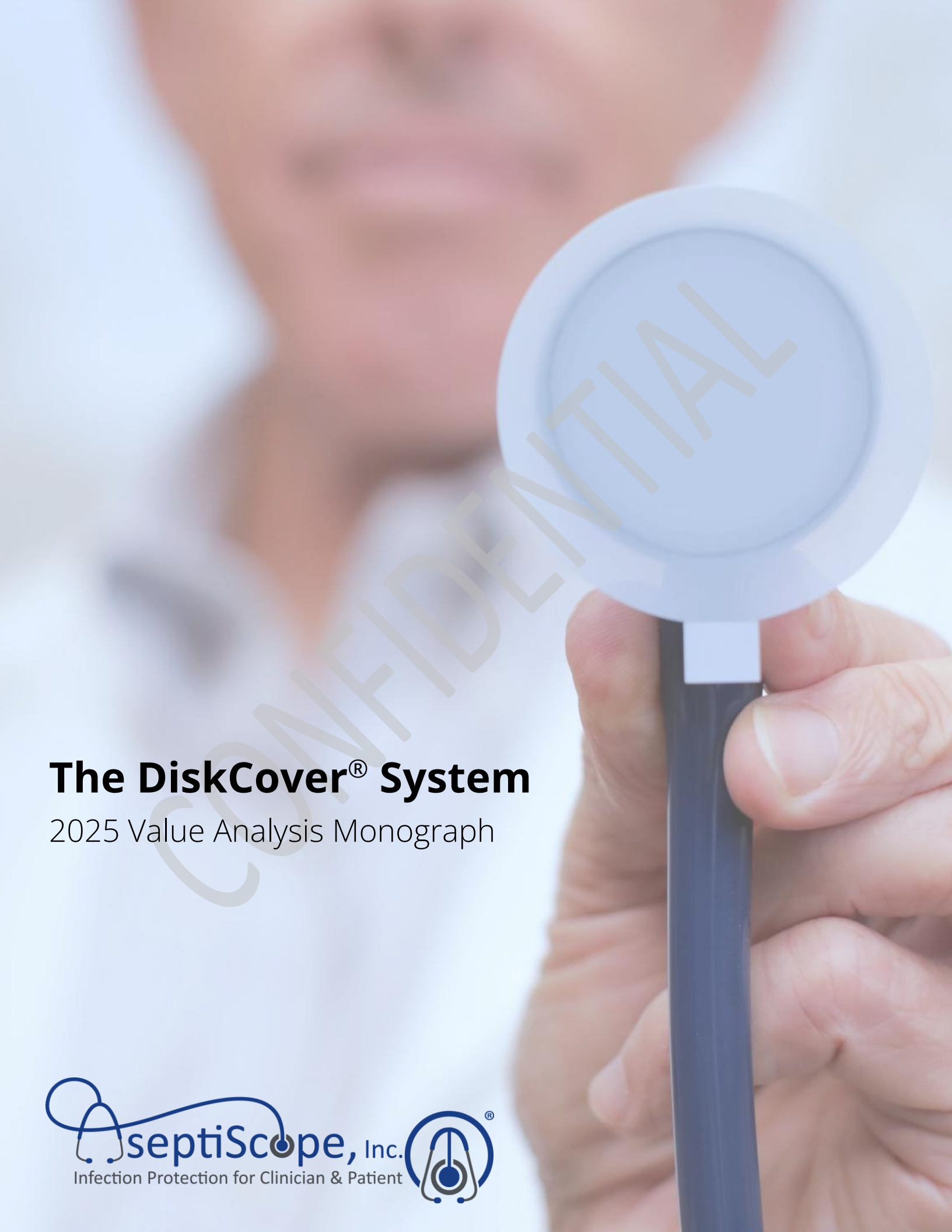

The DiskCover® System

2025 Value Analysis Monograph

AseptiScope, Inc.®

Infection Protection for Clinician & Patient

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Contents

I. Executive Summary

AseptiScope® Inc., is a privately funded San Diego based company founded in 2016 and led by clinical innovation experts, leading medical researchers, and practicing physicians. The company's leadership includes a seasoned team with a successful track record of working together to deliver blockbuster product introductions of clinically proven therapeutics and technologies. AseptiScope is driven to bring forward novel solutions that ensure "Infection Protection for Clinician & Patient."

AseptiScope's mission is to bring a higher standard of infection control to healthcare, while saving time for healthcare providers through the introduction of touch-free dispensers that provide aseptic barrier protection for common, highly contaminated vectors.

The DiskCover® System, AseptiScope's flagship product, provides value as the first true, evidence-based solution for the threat of stethoscope contamination, addressing pathogen transmission and saving time for clinical care.

The stethoscope, often referred to as the "clinician's third hand," due to it hosting the same levels and diversity of pathogens as the fingertips,[1] is a highly contaminated vector without an effective cleaning solution. While hand hygiene standards and protocols are highly elevated within the clinical setting, no similar standards for stethoscope hygiene exist.

Analysis of the longstanding problem of the stethoscope diaphragm as a vector for pathogen transmission helps elucidate the need for a new, effective, standardized, and measurable solution. The Institute for Healthcare Improvement (IHI) has used improvement science to advance and sustain better outcomes in health care.[1] The DiskCover System is a technological advancement which contributes to achieving the IHI Triple Aim: improved quality of care at a reduced cost and with an improved patient experience.[2]

Only With The DiskCover® System, Stethoscopes Are Now **Touch-Free**

Product Overview

The DiskCover System is AseptiScope's evidence-based solution to combat the longstanding, unaddressed, and increasingly prominent threat of healthcare-associated infections (HAIs) transferred by stethoscope contamination.

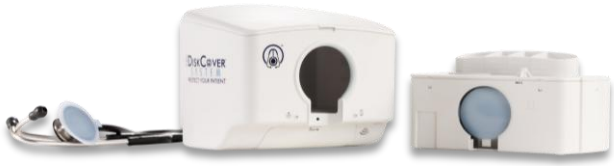
The system works by dispensing a single-use barrier that is easily applied to the diaphragm of a stethoscope and, later, effortlessly removed for disposal after each patient interaction. Disk covers are proven to be acoustically invisible and therefore do not diminish the quality of stethoscope sound transmission,[3] and work to prevent pathogen transfer from stethoscope to patient, as well as between clinicians. With The DiskCover System, stethoscopes are now touch-free for patients.

The dispenser itself uses advanced touch-free motion sensor technology to ensure health care professionals have an aseptic surface for every patient-stethoscope interaction. Not only is it effective, it is quick, easy to use, inexpensive and requires no formal training.

Product Information

The DiskCover System includes a wall-mounted dispenser that houses a Clean Cassette® containing single-use disk covers:

- Fits on leading adult and pediatric stethoscope diaphragms, regardless of shape (NICU stethoscopes currently not supported)
- Acoustically invisible
- Medical grade
- Biocompatible
- Latex-free
- Leaves no residue upon removal



Intended Use

The DiskCover System automates the touch-free application of single-use disk covers to stethoscope diaphragms as an aseptic barrier to prevent patient exposure to harmful pathogens and contaminants.

Automation of Aseptic Technique

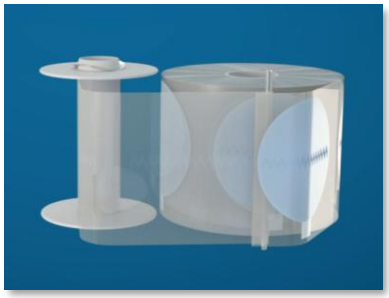
An Aseptic Patient Contact Every Time

Aseptic technique is the gold standard for preventing pathogen transmission with central lines and surgical sites.[4] However, its resource and time intensity typically makes it impractical for broad application.

The DiskCover System automates aseptic technique for stethoscope hygiene, enabling an aseptic auscultation contact for a patient for every examination.

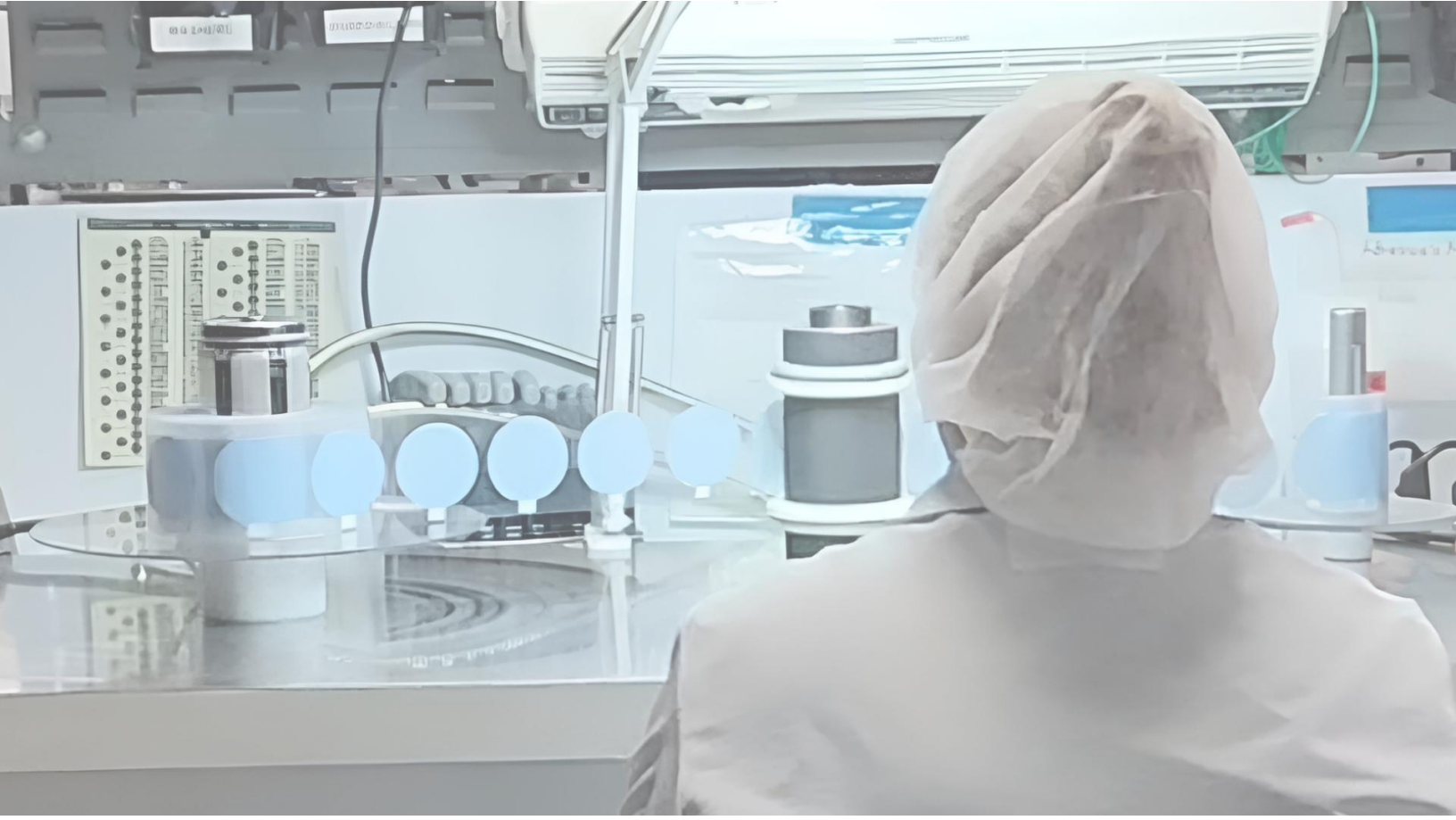
Key Design Components:

- **420 Single Use Disk Cover Barriers:**
  An aseptic carrier tape maintains each disk cover housed inside the tape roll within the clean cassette. Barriers are protected from exposure until the moment of use.



- **Touch-Free Delivery of Single-Use Disk Covers**:
  As the clinician activates the dispensing system, the single use disk cover barrier is forwarded into the application window from the roll.

- **Aseptic Stethoscope Application:**
  The stethoscope facing side is at that moment exposed for touch-free stethoscope application. The patient facing side remains protected until removed from the system.



Automation of Aseptic Technique

Clean Room Assembly & Shipping:

Single-Use Barriers Assembled and Maintained as Aseptic:

- **Each Disk Cover barrier** is produced in protected rolls of 420 barriers. Derived and assembled in clean rooms, using certified 3M conversion processes. An aseptic carrier shields each of the single-use, disk cover barriers as fully contained.
- **Clean Cassette assembly** also takes place in clean room conditions and offers a second layer of protection against any environmental conditions. Once assembled, these cassettes are enclosed in individual clean wraps prior to shipping to customers.
- **The Clean Cassette** housing interfaces with the wall mounted dispensing unit to maintain aseptic conditions and ensure touch free automation. Handling the clean cassette ensures that the tape roll remains in protected conditions, and the tape roll ensures each of the 420 disk cover barriers remains aseptic.

Automation of Aseptic Technique

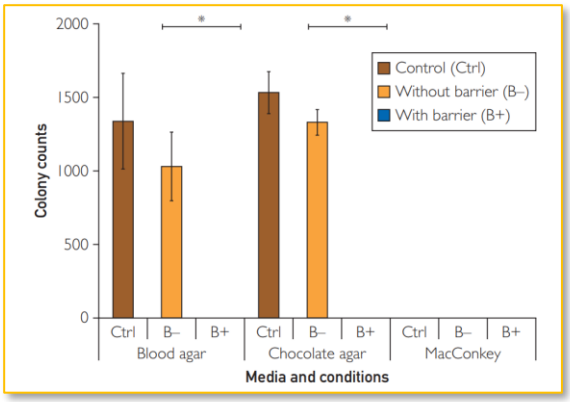
Validation - Controlled Studies and Clinical Use:

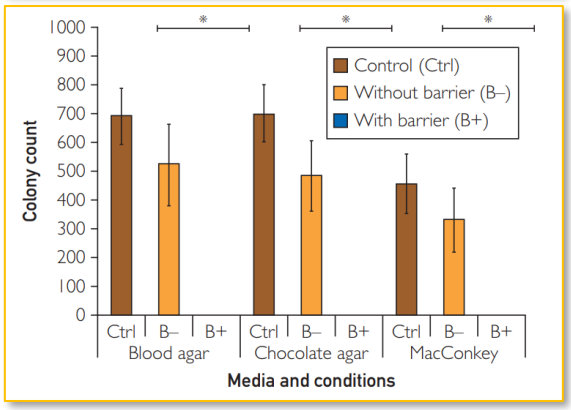
The aseptic nature of disk covers is supported by published evidence and data.

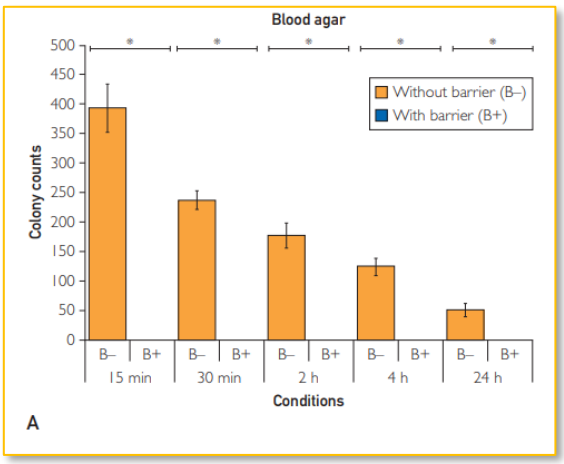
Multiple controlled studies have demonstrated that each disk cover barrier is impervious to all pathogens ever studied. When compared to controls, as well as unprotected stethoscope diaphragms, patient exposure to all pathogens remains at zero, ensuring a clean point of contact.[5, 6]

A Range of Conditions: These studies have not only assessed barrier effectiveness against a full range of pathogens, including MDROs (multi-drug resistant organisms) and alcohol resistant pathogens, e.g., *C. difficile*, but also against contaminated patient samples that have been known to contaminate diaphragms when used in trauma, Long Term Care (LTC), and high acuity settings. Tested sources have included saliva, stool, as well as infected samples of blood, urine and sputum.

Robust During Temporal Testing:
The unique disk cover barrier has also been demonstrated to offer robust protection over hours up to a full day of testing for *C. diff*, and up to a week for infected blood, sputum, urine, and feces samples, while colony counts are known to thrive on stethoscopes. This provides effective barrier control during the examination of patients.







Mayo Clin Proc Innov Qual Outcomes. 2020;4(1):21-30.

American Journal of Critical Care

"Reduction of ICU CLABSI Rates by Integrating Stethoscope Hygiene Innovation and Dressing Standarization into a Prevention Bundle"

Automation of Aseptic Technique

Customers Are Seeing the Impact of Fast and Effective Stethoscope Hygiene with The DiskCover System

Central Line Infections and Stethoscope Hygiene:

Historically, stethoscope hygiene has been neither convenient nor effective. However, when an infection prevention director in Memphis Tennessee encountered an unacceptable CLABSI rate in her ICU, she identifed that poor stethoscope hygiene was an unaddressed concern. See section "HAI Prevention Bundle" (Page 30) for more details.

Reduction of ICU CLABSI Rates by Integrating Stethoscope Hygiene Innovation and Dressing Standardization into a Prevention Bundle

Naomi Ragsdale, BSN, RN, Wendy Simpson, MSN, RN, CCRN
Lt. Col. Luke Weathers, Jr. (Memphis) VA Medical Center, Department of Infection Control

Purpose/Rationale

Due to increasing ICU CLABSI rates between 2021-2022, we aimed to assess the impact of an intervention bundle that included a standardized CHG-impregnated dressing and a new evidence-based stethoscope hygiene practice.

Synthesis of Evidence

We performed a PubMed systematic review for results between 2020-2022 using the search terms "disposable stethoscope" and "CHG impregnated dressing". There was no evidence of infection control efficacy with disposable stethoscopes, although three articles supported the use of touch-free diaphragm barrier systems.[1-3] Three articles reinforced CHG-impregnated dressing for preventing central line infections.[4-6]

Practice Change

We implemented a CLABSI prevention bundle in an 18-bed high acuity ICU from March 2022 to current date. The bundle included daily nursing and infection prevention rounds, daily line checks, alerts for ordered blood cultures, prompt central line downgrades, and education of all staff. We began standardization of CHG-impregnated dressings for all central lines and standardized all insertion and dressing change kits. We installed automated aseptic stethoscope barrier dispensers in each room and decreased the use of disposable stethoscopes.

Figure 1: Touch-free diaphragm barrier system for stethoscope hygiene.

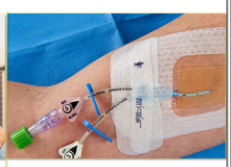


Figure 2: Standardized, CHG-impregnated dressing.

Implementation Strategies

Standardization of CHG dressings and kits across all dialysis and central lines was implemented, along with staff education on aseptic technique and ongoing rounding. Additional strategies included placing the stethoscope barrier system in patient rooms near the hand hygiene station for maximum use. Instruction placards were placed above each system as reminders. Surveys were deployed to collect clinician feedback and refine the implementation processes. ICU champions were appointed to ensure continued adoption of all bundle elements.

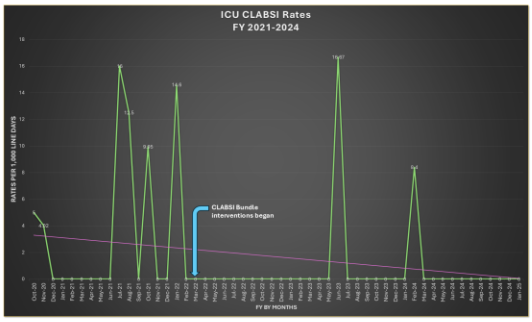


Figure 3: ICU CLABSI rates per 1,000 line days from FY 2021 to FY 2024, demonstrating a declining trend following the implementation of CLABSI bundle interventions in March 2022 (indicated by the blue arrow). The overall decrease (indicated by the purple trendline) highlights the impact of the bundled implementation strategies.

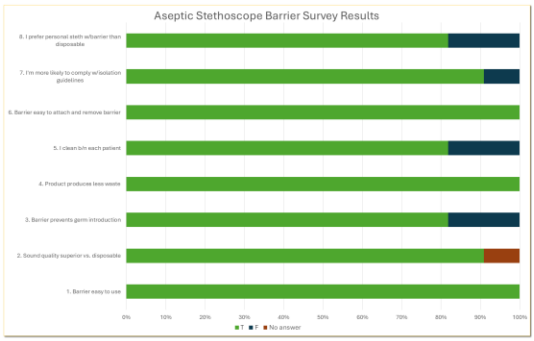


Figure 4: Survey results on aseptic stethoscope barriers, highlighting clinician preferences and perceptions across various metrics including ease of use, sound quality, prevention of germ introduction, and compliance with isolation guidelines. The results demonstrate strong overall satisfaction for the barrier's utility and effectiveness.

Evaluation

The post-implementation group had a significant reduction in CLABSI rates, from average 3.88 to 0.93 infections per 1,000-line days. The CHG-impregnated dressing eliminated the problem of staff not addressing compromised dialysis dressings. As all central lines were now changed using the same kit and dressing, compliance was 100%. Clinician survey responses regarding stethoscope hygiene innovation reported implemented systems were easy to use, and the majority believed the new hygiene method was superior to disposable stethoscopes.

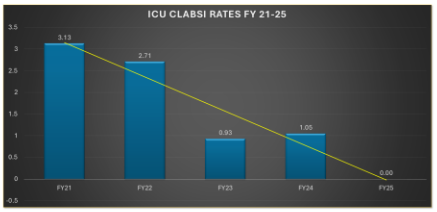


Figure 5: ICU CLABSI rates from FY 2021 to FY 2025, showing a significant and consistent decline over the years. The implementation of a CLABSI bundle is reflected in the downward trend, with rates reaching 0.00 in FY 2025.

Implications for Practice

We found that a CLABSI bundle that included an aseptic stethoscope hygiene barrier and a standardized dressing and kit was effective in decreasing infection rates. Furthermore, removal of the disposable stethoscopes resulted in clinician satisfaction improvement. The next steps involve expanding the system's use hospital wide.

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VA U.S. Department of Veterans Affairs

Disclosures: No conflicts of interest to disclose. | **Contact Information:** wendy.simpson1@va.gov

The **Clinician's Third Hand**: Stethoscope Diaphragm

II. Clinical Data

There is mounting clinical evidence that demonstrate:

- the stethoscope is a vector for pathogen transmission
- the inadequacy of current stethoscope hygiene strategies
- the low compliance of current stethoscope hygiene standards

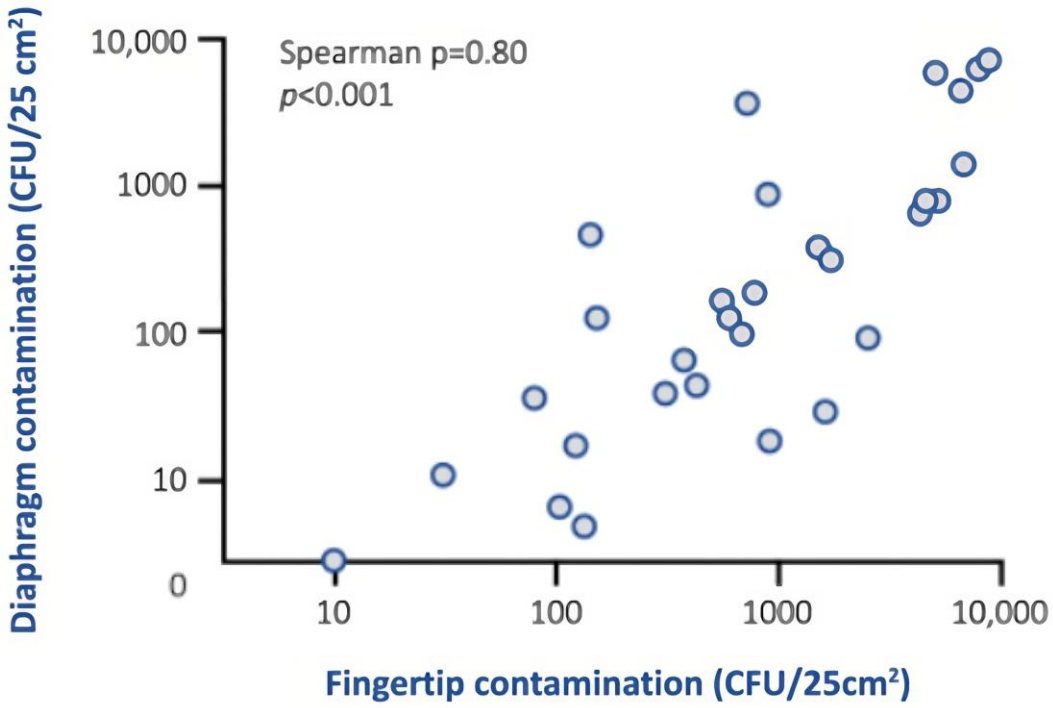
Ultimately, guidelines for stethoscope hygiene are emerging that emphasize the efficacy of and need for a new standard of stethoscope hygiene through aseptic stethoscope diaphragm barriers.

Stethoscopes as a Vector

The stethoscope diaphragm, often referred to as the "clinician's third hand" because it hosts the same levels and diversity of pathogens as the fingertips,[7, 8] is a highly contaminated vector without a hygiene solution. Hand hygiene interventions are commonly linked to infection reduction without mention of other prevention strategies.[9] However, prevention of HAIs requires multiple concurrent interventions.[10, 11] While hand hygiene standards and protocols are highly elevated within the clinical setting, few such standards for stethoscope hygiene exist.

Stethoscope and Fingertip Contamination Levels **Strongly Correlated**[7]

The STETHOSCOPE DIAPHRAGM carries the same volume and diversity of pathogens as the FINGERTIPS[7]



Mayo Clin Proc. 2014;89(3):291-299

There are over 5.5 billion annual auscultations in the United States alone.[12] Despite progress with hand hygiene as the foundation of infection control, the USA still sees nearly 400,000 HAI deaths per year.[8, 13] The stethoscope undermines these efforts and represents a "weakness in hospital infection prevention practices." [5, 8]

Evidence Supports “Stethoscope as a Vector”

These findings are not controversial. There are a multitude of clinical and scientific publications that establish the stethoscope as a major vector of pathogen transmission. The following list represents the totality of the literature resulting from a pub med systematic review performed on March 22, 2025, using the search term “**Stethoscope as a Vector.**”

The full list of references from the performed search is available for access (CLICK)

Inadequacy and Low Compliance of Current Standards

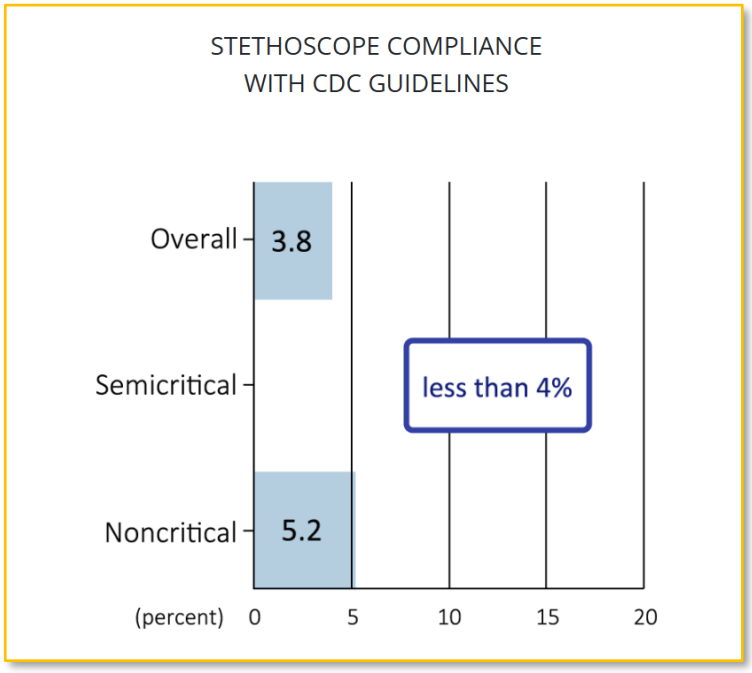
Given the vast amount of evidence provided thus far on the risks of the stethoscope as a vector for pathogen transmission, new standards for stethoscope hygiene should be set in place and elevated to standards for hand hygiene.

The current common methods of stethoscope hygiene, that attempt to address the stethoscope as a vector of pathogen transmission, involve either cleaning with a disinfectant wipe or alcohol-based hand rub (ABHR), or using single-use/single-patient disposable stethoscopes.

Not only are both these methods inadequate in providing an aseptic stethoscope diaphragm surface for auscultation, they also still provide significant risks of pathogen transmission.

Cleaning with disinfectant wipes/ABHRs disrupts clinician workflow, and compliance is low.

One of the current methods of stethoscope hygiene is cleaning the diaphragm with a disinfectant wipe. This process should take a full minute to do correctly, which interrupts clinician workflow and presents an inherent difficulty for compliance.[8, 14] In a hospital observational study, clinicians were observed and stethoscope hygiene practices were recorded. Stethoscopes were disinfected, per CDC guidelines, in less than 4% of encounters and were not disinfected at all in 82% of encounters.[15]

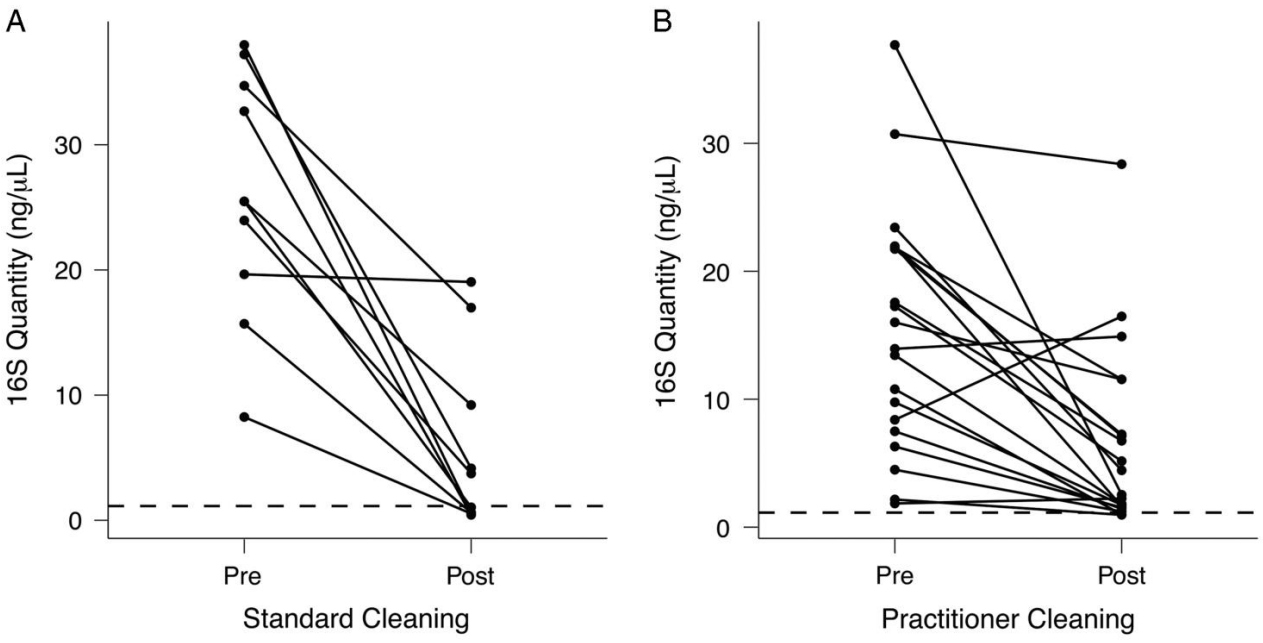


Cleaning with disinfectant wipes/ABHRs does not entirely eliminate pathogens.

Even when wiped down correctly for 60 seconds between each patient, cleaning with disinfectant wipes has been shown to decrease but not eliminate pathogens on the diaphragm.[8, 14] In fact, not only is cleaning with alcohol wipes ineffective for most pathogens, in several studies it can actually increase levels of *C. diff* on the stethoscope diaphragm.[8, 16]

PATHOGENS FREQUENTLY PERSIST AFTER CLEANING

Stethoscope contamination is reduced but not eliminated after cleaning[14]



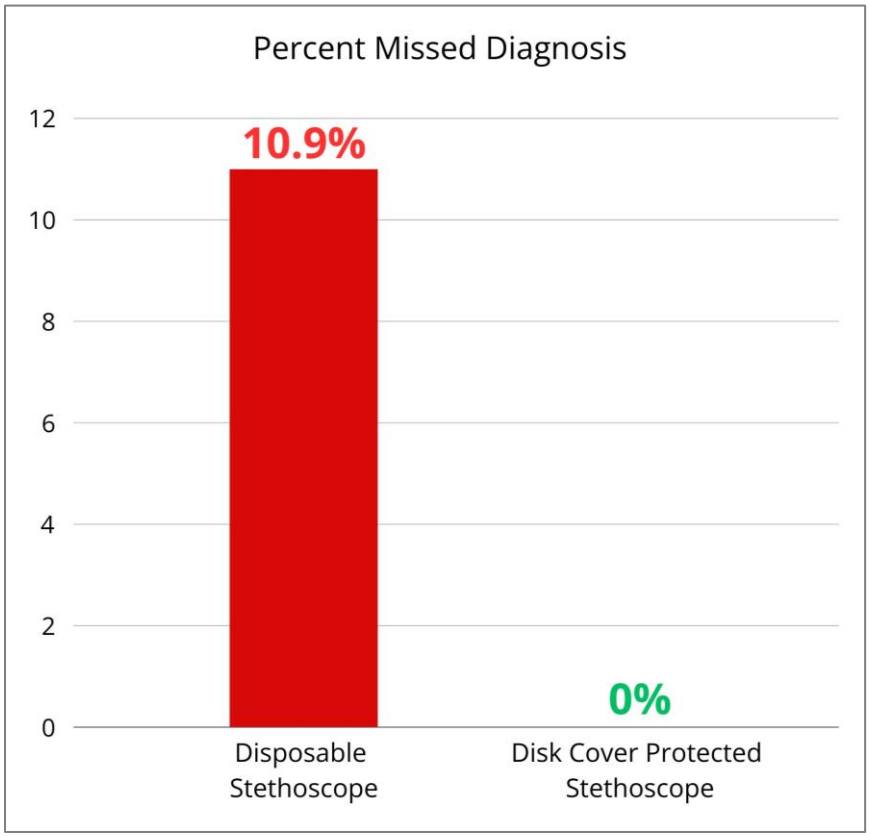
Standard cleaning for 60 seconds returned only **50%** of stethoscopes to the level of clean. Meanwhile, practitioner cleaning (method and time varied), returned only **10%** of stethoscopes to the level of clean.[14] In some occurrences, the contamination level of the stethoscope *actually increased* after practitioner-preferred cleaning.

Disposable stethoscopes reduce auscultation quality and have a high potential to cause harm.

The other common method of stethoscope hygiene are the single-use, single-patient, or patient room, disposable stethoscopes.

In a study where clinicians auscultated a Simulation Mannequin with disposable stethoscopes, they misdiagnosed cardiac murmurs 10.9% of the time, consisting of misinterpretation of 9 diastolic and 3 systolic murmurs.[3] Because diastolic murmurs are a major predictor of a heart failure diagnosis, the misinterpretation caused by a disposable stethoscope would effectively delay a diagnosis in heart failure. Unfortunately, research shows that increased time taken in diagnosing heart failure correlates with increased mortality rate.[17]

Disposable Stethoscopes Potential Number Needed to Harm (NNH) = 11

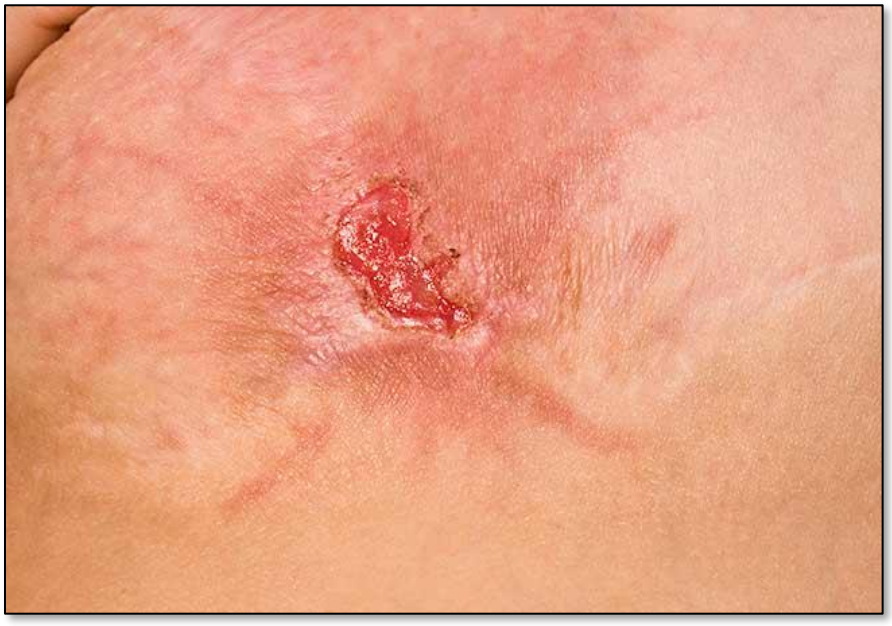


Disposable stethoscopes are colonized with nosocomial pathogens after use.

Practitioner and patient room stethoscopes are colonized with nosocomial pathogens. Samples from intensive care unit practitioner and single-use stethoscopes were observed to have significantly higher quantities and diversities of bacteria than new, unused disposable stethoscopes.[5] In a study, MRSA and *Pseudomonas leuteola* were cultured from personal and intensive care unit shared stethoscopes, respectively, posing an additional safety concern for contamination between clinical staff who share disposable stethoscopes.[18]

Therefore, to effectively practice safe stethoscope hygiene via disposable stethoscopes, hospitals would need to require disposal of these tools immediately after the first use, which could be an extremely expensive protocol to carry out.

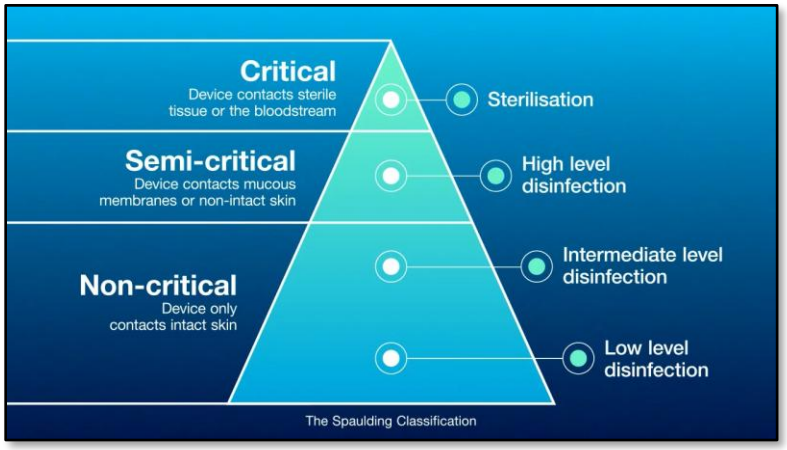
MRSA infections are a significant HAI prevalent in healthcare settings[19]



Not A "Non-Critical" Item:

The Stethoscope Diaphragm

Spaulding Classification Limitations



The Spaulding Classification, originating back in 1939, is still used in the CDC's 2008 guidance on stethoscope hygiene which designates the stethoscope as a "Non-critical" item that only requires a low level of disinfection, due to its intended contact being with intact skin. Studies in recent times have identified some archaic aspects of Spaulding's classification system.[20] As for how the system classifies stethoscope diaphragms, it is ultimately a misleading label as it does not account for **a)** contemporary data outlining the potency of the diaphragm as a vector and the inefficacy of cleaning solutions, and **b)** situations where stethoscopes are used in categories with **non-intact skin**.

Examples of stethoscope use in categories with non-intact skin:

- **PACU:** Post-anesthesia care unit, assessment emerging from anesthesia and recovery from surgery
- **Labor and Delivery:** Where Semmelweis first described puerperal fever and the value of hand washing
- **SICU**: Surgical Intensive Care Unit, caring for patients with lacerations/surgical sites
- **Transplant floor:** Where everybody is on major immunosuppressant medications
- **ICU/CCU settings:** Central lines with openings inviting pathogens
- **Oncology floor:** Another entire cohort taking immunosuppressant medications
- **Emergency:** All patients sick enough to be admitted to the hospital go through the ER
- **Internal Medicine Floor:** Where patients have bedsores, shared rooms, and frequent pathogen exposures
- **Surgical floors:** Orthopedics, general surgery, plastic surgery, endocrine, neurosurgery, ENT, Urology, and Cardiothoracic patients, all without intact skin
- **Dialysis:** Fistula identification where needles are inserted into patients every few days
- **Burn Unit**: Where patients have no skin

A New Normal for The Clinician's Third Hand

Unmet Clinical Needs

Given the inadequacy of current practices of stethoscope hygiene, the need for a new and effective, standardized, and measurable solution is elucidated. A new standard practice should aim to solve all the previous issues outlined with current standards.

It should aim to prioritize patient and clinician safety through complete reduction in any possible pathogen or contaminant transmission from the stethoscope diaphragm to another surface.

Workflow compatibility is a requirement to not only maintain high compliance, but also liberate clinicians to allocate their time toward patient care.

Finally, high auscultation quality offered by a high-fidelity stethoscope should not be sacrificed for a reduction in pathogen transmission.

A complete, aseptic technique for auscultation using a stethoscope is greatly needed in the clinical environment.

The DiskCover System Key Features

The DiskCover System was carefully designed to fill the gaps in current methods of stethoscope hygiene and meet the needs of a clinical solution that did not yet exist prior to its introduction.

Automated, touch-free	Automated and advanced sensor technology allows for touch-free application of a disk cover to a stethoscope diaphragm, ensuring aseptic technique.
Instant application	Clinician users report The DiskCover System is workflow compatible, easy to use, and requires no formal training to apply an aseptic barrier to stethoscopes within seconds,[21] allowing additional time for patient care.
Acoustically invisible	No statistically significant difference could be found between sound files produced by auscultating a Simulation Mannequin with an electronic stethoscope and the same electronic stethoscope protected by a disk cover.[3]
Superior to disposable stethoscopes	Disposable stethoscopes have a high potential to cause harm. In a study, clinicians who auscultated a Simulation Mannequin with disposable stethoscopes misdiagnosed 10.9% of the time, while clinicians with a high quality stethoscope, as well as with a high quality stethoscope protected by a disk cover, had 100% accuracy in diagnostics through auscultation.[3]
Provide an aseptic surface for auscultation	Disk covers have been shown to block 100% of pathogens found in stool, saliva, as well as infected blood, sputum, and urine.[5]
Protect from *C. diff* transmission	Disk covers have been shown to completely block *C. difficile* in vitro.[22]
Excellent enabler of antimicrobial stewardship	Assembly in a cleanroom environment with the intentional exclusion of antimicrobials ensures an aseptic barrier for the stethoscope diaphragm that does not give rise to multidrug resistant organisms.

Table. Comparison of Stethoscope Hygiene Attributes[8]

	Stethoscope Hygiene Strategies		
Attribute	**Isopropyl Alcohol Wipes**	**Single Use Stethoscopes**	**The DiskCover System**
Rapid to use (<2 seconds)	**NO**	**YES**	**YES**
Prevents between patient contamination	**NO**	**YES**	**YES**
Always provides aseptic patient contact	**NO**	**NO**	**YES**
May transfer pathogens between staff	**NO**	**YES**	**NO**
Impairs auscultation	**NO**	**YES**	**NO**
Inexpensive (<50 cents)	**YES**	**NO**	**YES**
Digital use compliance monitoring	**NO**	**NO**	**YES**
Remote supply status monitoring	**NO**	**NO**	**YES**
May harm stethoscope tubing	**YES**	**NO**	**NO**
Evidence of increasing *E. faecium* resistance	**YES**	**NO**	**NO**
Evidence of increased *C. difficile* sporulation	**YES**	**NO**	**NO**
May allow *C. difficile* transfer between patients	**YES**	**NO**	**NO**
Evidence of increased *A. baumannii* growth	**YES**	**NO**	**NO**

III. Value Analysis

Overview

Multiple publications confirm that the stethoscope diaphragm is a highly contaminated vector and likely responsible for a significant number of infections. Furthermore, literature shows that current hygiene practices with alcohol-based hand rubs (ABHRs) do not eradicate the most virulent pathogens, e.g., multidrug-resistant organisms (MDROs) and *Clostridioides difficile (C. diff)*, leaving patients exposed to potentially harmful pathogens. The DiskCover System provides an aseptic, single-use disk cover that prevents patient exposure to even the most resistant pathogens, and reduces cost per capita, achieving the Institute for Healthcare Improvement's (IHI) Triple Aim.[1]

Readmissions and Healthcare Associated Infections (HAIs) are both important factors in the Centers for Medicare & Medicaid Services' (CMS) determination of reimbursement penalties.[23] A single HAI can cost an institution thousands of dollars. For example, a single *C. difficile* infection can cost a facility over $90,000.[8, 24] This is because nosocomial infections are associated with both increased resource utilization and increased length of stay.[25]

Given the overwhelming data on the stethoscope diaphragm as a vector, as well as the mounting evidence supporting the efficacy of aseptic barriers for stethoscope diaphragms, adoption and introduction of The DiskCover System in the clinical environment is very likely to have a significant, cost-saving economic impact for hospitals through its prevention and reduction of HAIs.

Cost Justification

The most immediate and obvious financial impact of The DiskCover System would be from the prevention of HAI.

While direct causative associations are not generally available for HAI impact with individual personal protective equipment (PPE), the stethoscope hygiene market has a very sharp contrast between standard of care alcohol based hand rubs (ABHRs) and The DiskCover System when it comes to the ability to reduce transmission of multidrug-resistant organisms (MDROs) and *Clostridioides difficile* (*C. diff*) within a hospital and the direct financial impact of this consequence.

C. diff is the leading cause of hospital-associated diarrhea in the United States and one of several HAIs targeted by the US Department of Health and Human Services in a 2013 action plan.[26] In 2017, it sickened more than 223,000 hospital patients, was associated with 12,800 deaths, and was responsible for more than $1 billion in attributable healthcare costs.[27]

While ABHRs have merely a weak impact on removing patient exposure to *C. diff* from the stethoscope diaphragm,[7, 14] and in fact have the potential to even exacerbate spread,[54] the DiskCover System has been demonstrated to be 100% effective in blocking pathogens and contaminants found on the stethoscope diaphragm, including *C. diff* and MRSA.[11, 22]

Given that an intervention study, where patients are randomized to pathogen exposure, is unlikely to be completed for ethical reasons, value modeling is appropriate. From a value-analysis perspective, single-use, aseptic barriers may be effective, as the avoidance of a single hospital acquired *C. diff* infection, with an estimated cost of $90,000,[8, 24] can underwrite over 250,000 auscultations with disk cover barriers.*

*Assumes list pricing for the Clean Cassette, your actual net price may be lower.

Significant CLABSI Rate Reduction

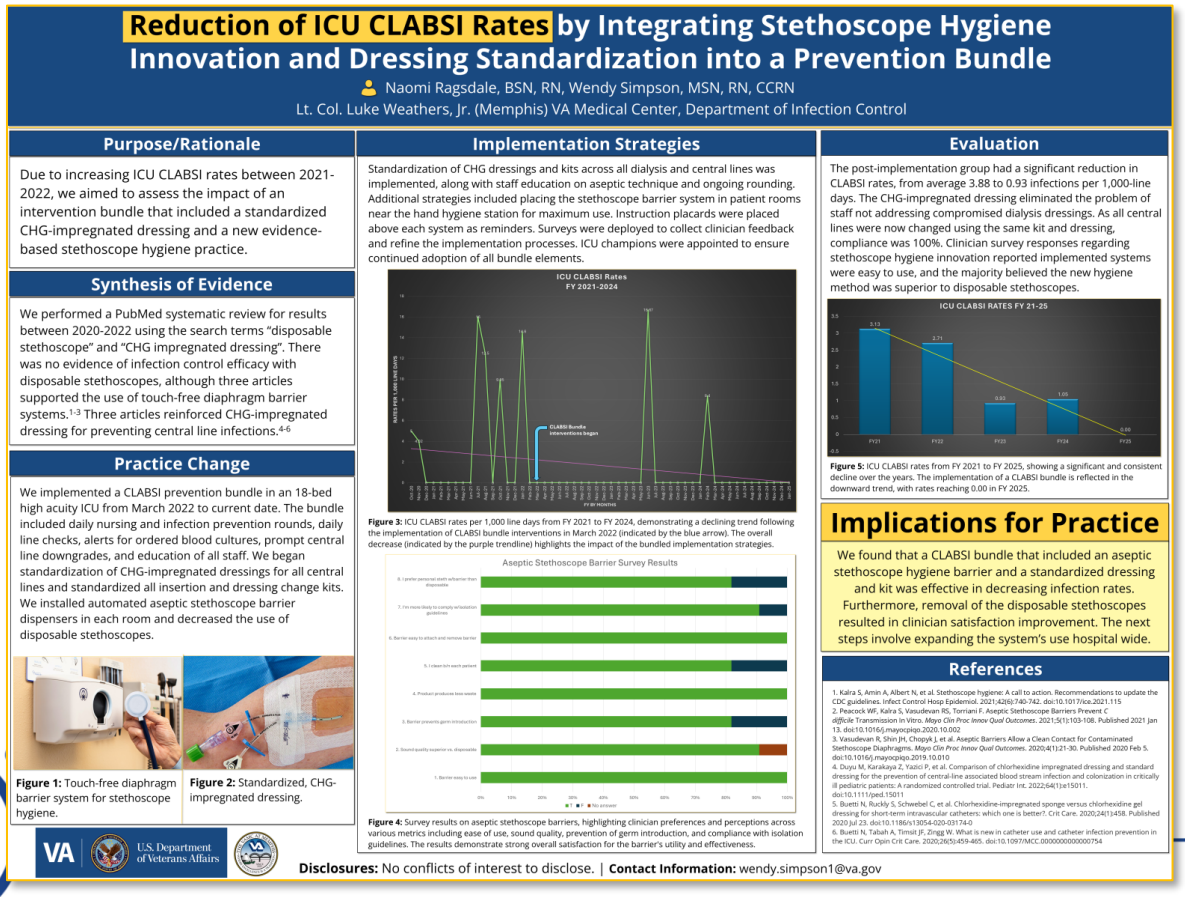
Through A DiskCover Bundle Approach

HAI Prevention Bundle

HAI prevention bundles, particularly ones that implement behavioral interventions, have demonstrated efficacy, and have even been recommended by the Institute for Healthcare Improvement (IHI).[28] Implementation of The DiskCover System into HAI prevention bundle interventions can encourage improved change in behavior by easing the difficulties of stethoscope hygiene and contribute to reduced HAI rates.

Not only this, The DiskCover System inherently automates aseptic technique for stethoscope hygiene, enabling clinicians to practice evidence-based technique in an easier and more effective way. This was demonstrated by a VA Health Medical Center, which conducted a central line-associated bloodstream infection (CLABSI) reduction quality initiative spanning from 2022 to 2024 in a high-acuity ICU. [29]

The quality initiative was submitted and accepted as a poster abstract at the 2025 AACN NTI Conference



Reduction of ICU CLABSI Rates by Integrating Stethoscope Hygiene Innovation and Dressing Standardization into a Prevention Bundle

Naomi Ragsdale, BSN, RN, Wendy Simpson, MSN, RN, CCRN

Lt. Col. Luke Weathers, Jr. (Memphis) VA Medical Center, Department of Infection Control

Purpose/Rationale

Due to increasing ICU CLABSI rates between 2021-2022, we aimed to assess the impact of an intervention bundle that included a standardized CHG-impregnated dressing and a new evidence-based stethoscope hygiene practice.

Synthesis of Evidence

We performed a PubMed systematic review for results between 2020-2022 using the search terms "disposable stethoscope" and "CHG impregnated dressing". There was no evidence of infection control efficacy with disposable stethoscopes, although three articles supported the use of touch-free diaphragm barrier systems.[1-3] Three articles reinforced CHG-impregnated dressing for preventing central line infections.[4-6]

Practice Change

We implemented a CLABSI prevention bundle in an 18-bed high acuity ICU from March 2022 to current date. The bundle included daily nursing and infection prevention rounds, daily line checks, alerts for ordered blood cultures, prompt central line downgrades, and education of all staff. We began standardization of CHG-impregnated dressings for all central lines and standardized all insertion and dressing change kits. We installed automated aseptic stethoscope barrier dispensers in each room and decreased the use of disposable stethoscopes.

Figure 1: Touch-free diaphragm barrier system for stethoscope hygiene.

Figure 2: Standardized, CHG-impregnated dressing.

Implementation Strategies

Standardization of CHG dressings and kits across all dialysis and central lines was implemented, along with staff education on aseptic technique and ongoing rounding. Additional strategies included placing the stethoscope barrier system in patient rooms near the hand hygiene station for maximum use. Instruction placards were placed above each system as reminders. Surveys were deployed to collect clinician feedback and refine the implementation processes. ICU champions were appointed to ensure continued adoption of all bundle elements.

Figure 3: ICU CLABSI rates per 1,000 line days from FY 2021 to FY 2024, demonstrating a declining trend following the implementation of CLABSI bundle interventions in March 2022 (indicated by the blue arrow). The overall decrease (indicated by the purple trendline) highlights the impact of the bundled implementation strategies.

Figure 4: Survey results on aseptic stethoscope barriers, highlighting clinician preferences and perceptions across various metrics including ease of use, sound quality, prevention of germ introduction, and compliance with isolation guidelines. The results demonstrate strong overall satisfaction for the barrier's utility and effectiveness.

Evaluation

The post-implementation group had a significant reduction in CLABSI rates, from average 3.88 to 0.93 infections per 1,000-line days. The CHG-impregnated dressing eliminated the problem of staff not addressing compromised dialysis dressings. As all central lines were now changed using the same kit and dressing, compliance was 100%. Clinician survey responses regarding stethoscope hygiene innovation reported implemented systems were easy to use, and the majority believed the new hygiene method was superior to disposable stethoscopes.

Figure 5: ICU CLABSI rates from FY 2021 to FY 2025, showing a significant and consistent decline over the years. The implementation of a CLABSI bundle is reflected in the downward trend, with rates reaching 0.00 in FY 2025.

Implications for Practice

We found that a CLABSI bundle that included an aseptic stethoscope hygiene barrier and a standardized dressing and kit was effective in decreasing infection rates. Furthermore, removal of the disposable stethoscopes resulted in clinician satisfaction improvement. The next steps involve expanding the system's use hospital wide.

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VA U.S. Department of Veterans Affairs

Disclosures: No conflicts of interest to disclose. | **Contact Information:** wendy.simpson1@va.gov

A Significant Reduction in CLABSI Rates:
Through a bundle approach combining standardized CHG-impregnated dressing with implementation of The DiskCover System, the clinical scene investigators were able to demonstrate a significant reduction in CLABSI rates, from average 3.49 to 0.97 infections per 1,000 line days. The researchers also reported a zero CLABSI occurrences within the last 10 months of the observation period. [29]

Furthermore, clinician satisfaction was evaluated. Their survey responses reported that the implemented systems were easy to use, and the majority believed the new hygiene method was superior to disposables stethoscopes.[29]

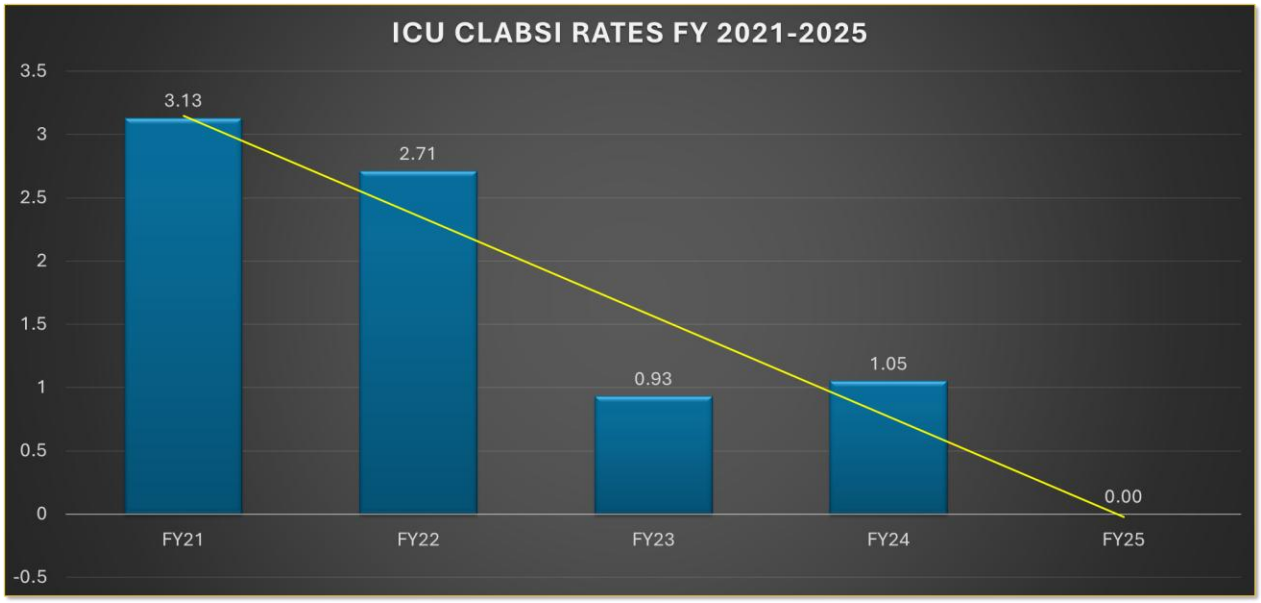


Figure: ICU CLABSI rates from FY 2021 to FY 2025, showing a significant and consistent decline over the years. The implementation of a CLABSI bundle is reflected in the downward trend, with rates reaching 0.00 in FY 2025.

Implications for Practice:
The investigators found that a CLABSI bundle, that included an aseptic stethoscope hygiene barrier and a standardized dressing kit, was effective in decreasing infection rates. Furthermore, surveys post-removal of the disposable stethoscopes resulted in improvement of clinician satisfaction. The next steps involved expanding the system's use of hospital wide.

Return on Investment Models

This section includes multiple models that reference cited literature to detail theoretical cost-savings attributable to adoption of The DiskCover System in the topics of cost and time-savings, HAI cost avoidance, and price comparison of previous standards of stethoscope hygiene. These models allow for variable inputs that can be tailored to the unique characteristics of a healthcare facilities and can be provided upon request to view how your facility might benefit financially through adoption of The DiskCover System. For this summary, a most-likely scenario using a 20-bed emergency department was used.

Acquisition Cost of The DiskCover System

The combined initial implementation and annual cost of The DiskCover System in this scenario would equal only $84,500.

Cost Avoidance from Time-savings

Cleaning the stethoscope diaphragm with alcohol adequately takes a significant amount of time out of a clinician's day that they could instead be dedicating to patient care.[8]

A model that observes the following factors outlines the costs associated with clinicians solely spent on stethoscope cleaning: [30]

- **Number of auscultating clinicians (nurses & physicians) in a department**
- **Number of patients seen per clinician in each department**
- **Average hourly cost of each clinician**
- **Hospital compliance rate of stethoscope hygiene**

Using an example of a high-acuity area, such as an Emergency Department, with 20 clinicians that each see an average of 20 patients a day,[31] and an average annual cost of $128,178.57 per clinician, this department if observing perfect stethoscope hygiene compliance would be spending **7300 hours on stethoscope hygiene a year**, with an **attributable cost of $449,857.49 per year** dedicated entirely to clinicians in this single department cleaning their stethoscope.

Stethoscope hygiene compliance is often much lower than 100%. At a more commonly observed 11% rate of compliance,[32] the department would instead be spending 803 hours on stethoscope cleaning, or $49,484.32 per year on clinician stethoscope cleaning.

While this model demonstrates that lower stethoscope hygiene compliance might be cost-saving in itself, the problem is that lower compliance will lead to much higher attributable costs, and potential mortality, from HAIs.

HAI Cost-avoidance

MRSA and *C. diff* are two examples of pathogens that have commonly been found on stethoscope diaphragms[33, 34] Hospital's attributable costs of these to HAIs can be significant, at an average of $14,792 per nosocomial non-pneumonia MRSA-related infection and $11,285 per nosocomial *C. diff* infection.

Theoretical pathogen transmission rate:

This model uses the following clinically referenced factors to outline the potential consequences of pathogen transmission occurrences via the stethoscope diaphragm and their associated attributable costs to the hospital:

- **Annual auscultations of the hospital / department being evaluated.**
- **Likelihood of C. diff (5%) or MRSA (7.4%) on a clinician's stethoscope diaphragm**[33, 34]
- **Hospital compliance rate of stethoscope hygiene (data suggests 11%)**[28]
- **Occurrence of pathogen transmission from a contaminated to a non-contaminated surface (40% for uncleaned stethoscopes; 5% for cleaned stethoscopes)**[35]

The model uses the above referenced data to calculate what percentage of these interactions will result in a transmission event of *C. diff* or MRSA. Using the previous example of a high-acuity emergency department with 20 clinicians each seeing 20 patients a day, the annual number of auscultations would provide 146,000 patient contacts. According to the model and data, these auscultations will result in **2,639** transmission occurrences of *C. diff* to the patient, and **3,906** transmission occurrences of MRSA.

Theoretical Infection Rate from Pathogen Transmission via Stethoscope Diaphragm

To convert *C. diff* transmission rate to *C. diff* infection rate, a variable factor must be used, as no clinical or scientific data exists on the transmission to disease conversion rates of pathogens for either the hands, fingertips, or the stethoscope diaphragm. Therefore, a sensitivity analysis was used to provide a theoretical infection range. The analysis uses a previously reported metric that 2.7% of United States adults are immunocompromised,[36] and these populations are at risk for a 100% sensitivity to infection from pathogen transmission.

Sensitivity Factor: An average patient will always have some sort of factor of sensitivity lower than that of a fully immunocompromised patient. In this case, the sensitivity factor is the % chance a patient becomes infected after being exposed to a pathogen, with 100% representing a completely immunocompromised patient.

- **Maximum sensitivity (100%):** An immunocompromised patient (2.7% of US adults) will most likely develop an infection if they experience a pathogen exposure. Theoretically, there is a 2.7% chance when auscultating a random patient that they are immunocompromised and, with a 100% sensitivity factor, will develop infection if they experience pathogen transmission from the stethoscope diaphragm. (For every 100 auscultation exposure = 2.7 infections)
- **Hospitalized sensitivity (10%):** An average hospitalized patient has a temporarily weakened immune system and is more vulnerable compared to their baseline health, but they may not be completely immunocompromised. They may experience a transmission to infection rate of 10% sensitivity factor compared to that of a fully immunocompromised patient, or 0.27% chance of infection per pathogen transmission. (For every 100 auscultation exposures = 0.27 infections)
- **Minimum sensitivity (1%):** A healthy patient, such as one simply being auscultated for a check-up, or one nearing full recovery, is much less likely to develop an infection from a pathogen transmission than either a hospitalized patient or a hospitalized immunocompromised patient. They may experience a transmission to infection rate of 1% (sensitivity factor) that of an immunocompromised patient, or a 0.027% chance of infection per pathogen transmission. (For every 100 auscultation exposure = 0.027 infections).

This same analysis was used for MRSA, except replacing one variable, that MRSA is a more common pathogen, and assumed there was a 7.4% likelihood of MRSA on a clinician stethoscope surface.[30]

Using the 2639 *C. diff* transmission and 3906 MRSA transmissions previously calculated, the theoretical rate of nosocomial infections per year due to transmission via stethoscope diaphragm are:

- **At 100% sensitivity factor: 71 *C. diff* infections and 105 MRSA infections**
  - **Total attributable costs: $2,365,554.78**
- **At 10% sensitivity factor: 7 C. diff infections and 11 MRSA infections**
  - **Total attributable costs: $236,555.48**
- **At 1% sensitivity factor: 1 C. diff infection and 1 MRSA infection**
  - **Total attributable cost: $23,655.55**

Price Comparison to Disposable Stethoscopes

A simple model compares hospital costs dedicated to purchase and use of single-patient, or disposable, stethoscopes to the acquisition and annual cost of The DiskCover System can help further highlight cost-savings.

A 50-bed emergency department spending an average of $6.00 per single-patient stethoscope on 4,000 patient admissions would be spending **$24,000 on disposable stethoscopes** over the year.

Summary

In conclusion, this model presents projected cost-avoidance from alleviation of time, HAIs, and current practices following integration of The DiskCover System into a facility. After considering the cost of acquisition of The DiskCover System, and the costs of maintaining alternate stethoscope hygiene methods, combining the highest probability scenario from each model yields an **annual cost saving of $355,043.36**. In addition to cost avoidance – compliance, protocolization, and standardization is made easy with The DiskCover System. The speed and ease of use of the system removes variation, and protocolization is made simpler and easier to enforce.

*Assumes list pricing for The DiskCover System, your actual net price may be lower

Vulnerable Patient Populations

Vulnerable patients such as elderly veterans, individuals undergoing transplant procedures, or those receiving cancer treatment have weakened immune systems and are more susceptible to HAIs.[37] Because of this, it is essential to protect them from potential sources of contamination within healthcare environments. Stethoscopes, which are used on multiple patients throughout the day and carry the same dangerous pathogens as the hands, pose a significant infection risk to these individuals.

Use of The DiskCover System can enable healthcare providers to minimize the risk of HAI for immunocompromised patients.

"Cancer patients are more susceptible to infection due to their course of treatment, stethoscope exams, and routine in patient assessment. We evaluated The DiskCover System and found it useful, practical, and functional. Importantly, it makes stethoscope hygiene more reliable and timely."

Gerardo Midence, MD

St. Joseph Cancer Center in Lewiston, Idaho

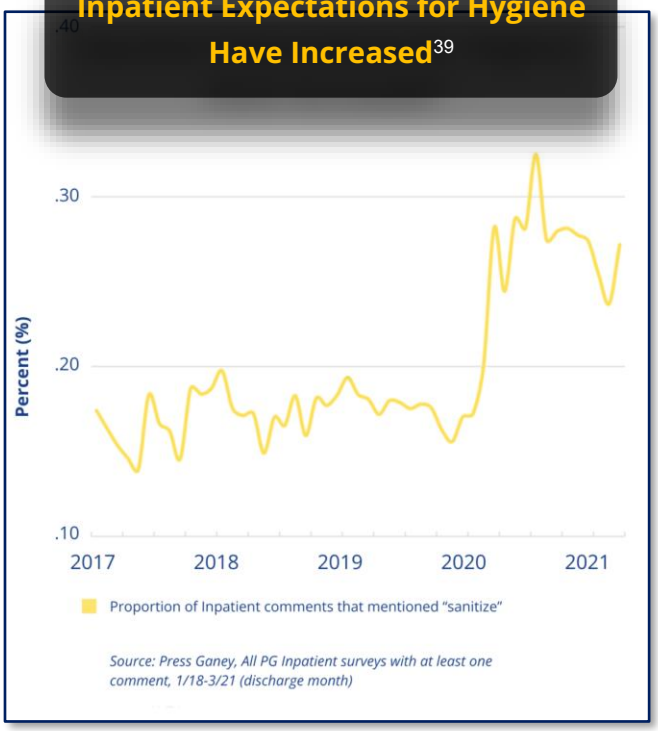
Addressing Growing Patient **Perceptions of Clean**

Patient Experience

Patient satisfaction has become an important metric for CMS reimbursement through the Value-Based Purchasing (VBP) program, which assesses hospitals on multiple performance domains, including patient satisfaction.[38] High patient satisfaction scores in the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey can improve hospital ratings, increase reimbursement, and enhance the overall reputation of the healthcare facility.

Patient experience data from Press Ganey and Compass One reviewing HCAHPS surveys have revealed inpatient expectations for hygiene have dramatically increased since the 2020 COVID-19 pandemic.[39] The report also highlights the importance to overall experience outcomes of addressing patients' perceptions of personal hygiene while in the healthcare setting, stating that expectations for hospital cleanliness and hygiene has gone from a baseline patient expectation to a core value that requires proof their hospital shares.

Inpatient Expectations for Hygiene Have Increased[39]



The DiskCover System provides a visible barrier against pathogens to make stethoscopes touch-free for patients. Applied at the point of care, patients can visibly see their healthcare providers demonstrate that they are prioritizing their safety. In a recent study conducted by the Cleveland Clinic, the aseptic diaphragm barrier system was shown to improve the patient experience measure via a visual impression that clinicians 'cared' about their patients.[40] This proactive measure can improve patients' perceptions of their safety and the overall quality of care, leading to higher satisfaction scores.

Environmental Sustainability

From the start of its development to its production and use today, The DiskCover System was designed with environmental sustainability as a major factor.

Disposable Stethoscopes Are Wasteful: 2.5oz of Unrecycled Material

A typical disposable stethoscope contains unrecyclable Acrylonitrile Butadiene Styrene (ABS) earpieces, Poly Vinyl Chloride (PVC) tubing, and Aluminum tubing, equating to 2.5oz of unrecycled material.[41]

ADC Proscope 664 Disposable Stethoscope Specifications

Chestpiece Type:	Diaphragm Only
Chestpiece Material:	ABS
Chestpiece Finish:	N/A
Chestpiece Weight:	.16 oz
Chestpiece Weight(gm):	4.5
Diaphragm Diameter:	1-3/4"
Diaphragm Diameter(cm):	4.45
Diaphragm Material:	PVC
Diaphragm Type:	Standard
Bell Diameter:	N/A
Bell Diameter(cm):	N/A
Headset Type:	Lightweight
Headset Material:	Aluminum
Headset Finish:	Anodized
Tubing Length:	21"
Tubing Length(cm):	53
Total Length:	32"
Total Length(cm):	81.25
Total Weight:	2.5
Total Weight(gm):	71
Scope Warranty:	1 Year

Material Volume Comparison
When evaluating the environmental impact of disk covers vs. the hypothesized equivalent use of disposable stethoscopes, it is clear disk covers represent a mere fraction of material waste that disposable stethoscopes occupy.

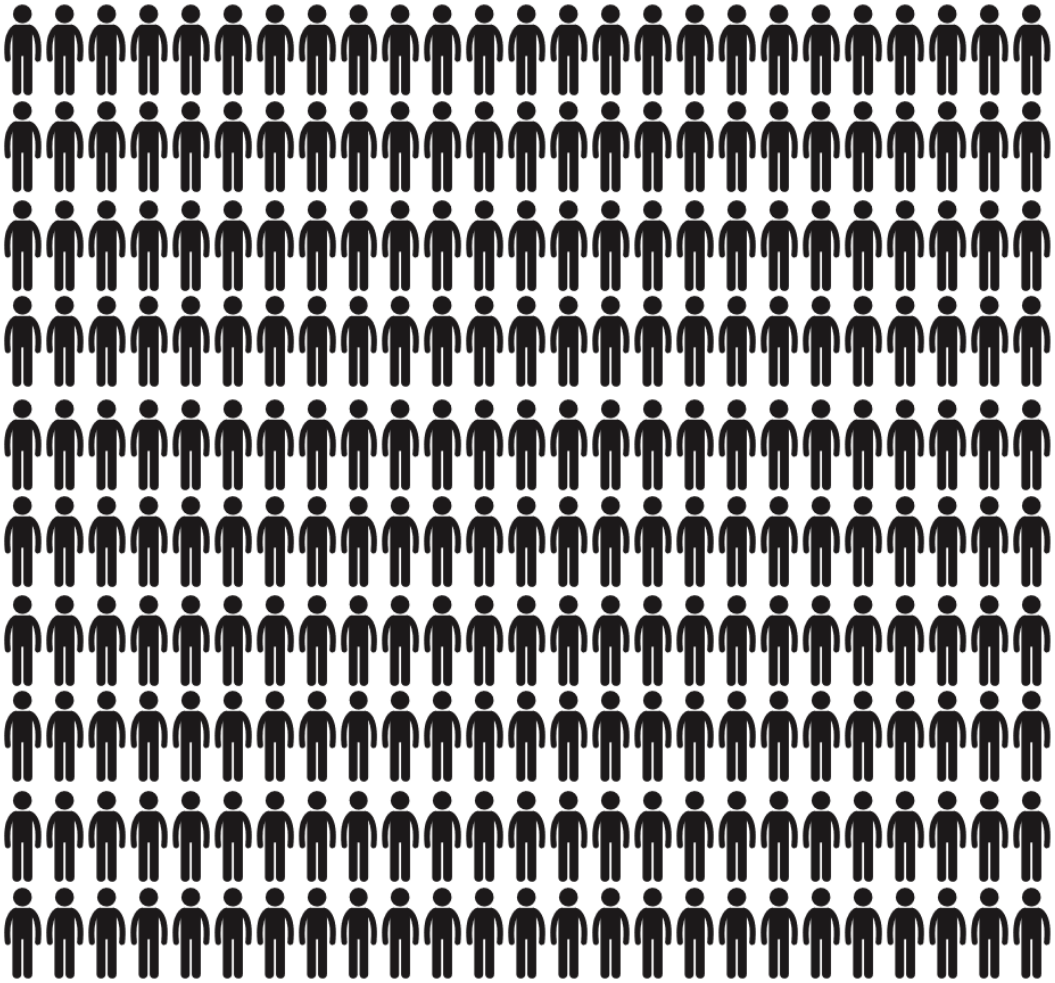
Hospitals should dispose of single-patient stethoscopes after discharge of the patient for whom the device was dedicated. A disposable stethoscope might typically be dedicated to a single patient for the full length of their stay. Assuming an average stay of 5 days, with an average auscultation number of 4 per day, each disposable stethoscope can then be compared to 20 disk covers.

With each disk cover being consisted of just 0.01oz of *recyclable plastics*, this means disk covers consist of < 0.5% of the material of a disposable stethoscope. Similarly, 20 disk covers equal just 8% of the materials used for a disposable stethoscope.[41, 42]

Sustainability of Disk Covers

A single disposable stethoscope (2.5oz of UNRECYCLED MATERIAL) can be used to auscultate 1 patient.

250 disk covers (2.5oz of Recyclable Plastic) can accommodate up to 250 aseptic, dedicated patient auscultations.



Recyclability of Disk Covers and Clean Cassettes

While it is recommended to dispose disk covers through hospital medical waste bins to maintain workflow compatibility and minimize risk of pathogen spread from used disk covers, disk covers are made from recyclable plastics.

Except for a small chip measuring a mere 0.184 in^2 in sectional area that must be disposed through appropriate electronic waste methods, The DiskCover System Clean Cassettes are made with 100% recyclable materials. AseptiScope offers multiple programs for customers to ensure that clean cassettes are recycled appropriately according to their local collection systems. Additional information is available upon request.

Antimicrobial Stewardship

Antimicrobial stewardship is a key component to preventing emergence of antimicrobial resistance.[43] Good antimicrobial stewardship promotes the appropriate use of antimicrobials to reduce microbial tolerance, resistance and cross-resistance, and decrease the spread of infections caused by multidrug resistant organisms (MDROs).[44]

The reason for this is very clear when reviewing the history in which alcohol and other antimicrobials have affected the human microbiome. Pathogens such as *C diff*, Carbapenem-Resistant Enterobacteriaceae (CRE), Vancomycin-Resistant Enterococci (VRE), and other resistant bugs exist because they are constantly exposed to antibiotics.[45, 46, 47]

Publications from recent years have been raising awareness to growing antimicrobial resistance attributable to the indiscriminate use of disinfectants in healthcare settings:

- **Disinfectants may exacerbate resistance to antibiotics:** In 2020, the advisory committee on disinfectants of the Health Council of the Netherlands performed an analysis on cases where disinfectants have led to antimicrobial resistance, and recommended implementation of policies to ***promote more prudent use of disinfectants***.[48]

- **Mechanisms of emerging resistance from disinfectants:** Multiple 2023 publications in *The Journal of Antibiotics* have analyzed the impact on antimicrobial resistance from non-antibiotic antimicrobial agents such as disinfectants and recommend that ***antibiotic stewardship programs should include disinfectants and biocides***.[49, 50]

Studies have also demonstrated that changes in the resistance of bacterial populations to isopropyl alcohol has occurred, concurrent with the nearly universal availability and use of alcohol-based hand rubs.[29] Alcohol is a prime example of a non-antibiotic antimicrobial agent whose its overuse has caused the development of resistant bacteria such as *E. faecium*.[51]

Disk Covers Contribute To **Better Antimicrobial Stewardship**

Reducing Stethoscope Hygiene's Previous Overreliance on Disinfectants

The DiskCover System is intentionally designed to remove the need for antimicrobials, and an over-reliance on indiscriminate use of disinfectants for stethoscope hygiene.

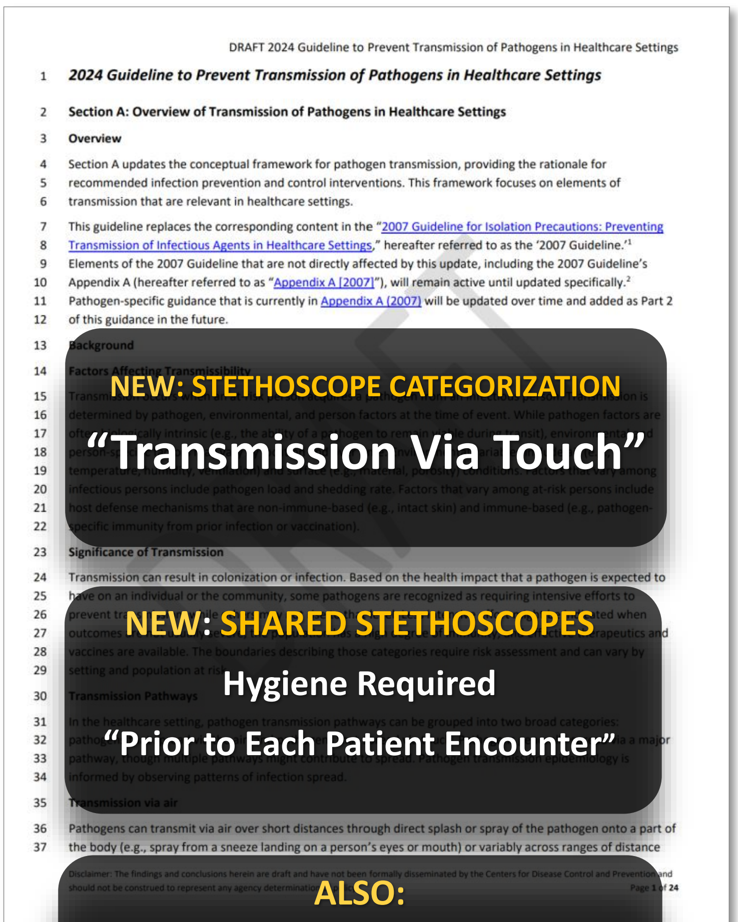
The use of aseptic barriers inherently excludes development of resistant pathogens and does not increase the probability of expanding MDROs. Disk cover barriers offer an aseptic surface and can be considered a tool consistent with quality antimicrobial stewardship practice.

Use of aseptic disk covers has been demonstrated to completely block transmission of bacteria commonly found on the stethoscope diaphragm with 100% efficacy.[5, 22] No literature exists suggesting that pathogens are able to adapt to penetrate physical barriers such as those dispensed by The DiskCover System.

CDC Elevates Stethoscope to Vector That **Transmits Via Touch**

New CDC Stethoscope Hygiene Guidelines

The CDC proposed revolutionary updates to stethoscope hygiene in the draft 2024 Guideline to Prevent Transmission of Pathogens in Healthcare Settings, newly categorizing the stethoscope as a vector that "transmits via touch" and putting it in the same transmission category as the hands. Additionally, these guidelines recommend that "stethoscope hygiene should be performed between each patient encounter." [52]



DRAFT 2024 Guideline to Prevent Transmission of Pathogens in Healthcare Settings

2024 Guideline to Prevent Transmission of Pathogens in Healthcare Settings

Section A: Overview of Transmission of Pathogens in Healthcare Settings

Overview

Section A updates the conceptual framework for pathogen transmission, providing the rationale for recommended infection prevention and control interventions. This framework focuses on elements of transmission that are relevant in healthcare settings.

This guideline replaces the corresponding content in the "2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings," hereafter referred to as the '2007 Guideline.'[1] Elements of the 2007 Guideline that are not directly affected by this update, including the 2007 Guideline's Appendix A (hereafter referred to as "Appendix A [2007]"), will remain active until updated specifically.[2] Pathogen-specific guidance that is currently in Appendix A (2007) will be updated over time and added as Part 2 of this guidance in the future.

Background

Significance of Transmission

Transmission can result in colonization or infection. Based on the health impact that a pathogen is expected to

Transmission via air

Pathogens can transmit via air over short distances through direct splash or spray of the pathogen onto a part of the body (e.g., spray from a sneeze landing on a person's eyes or mouth) or variably across ranges of distance

NEW: STETHOSCOPE CATEGORIZATION

"Transmission Via Touch"

NEW: SHARED STETHOSCOPES

Hygiene Required

"Prior to Each Patient Encounter"

ALSO:

"Dedicated Equipment may reduce transmission"

The DiskCover System:

Makes Stethoscopes Touch-Free For Patients

The DiskCover System:

Immediate Application Before Every Patient Encounter

Each Aseptic Single-Use Disk Cover:

Is dedicated to a single patient auscultation

CDC Engages AseptiScope

On Infection Control

CDC Division of Healthcare Quality & Promotion

In June 2024, AseptiScope was invited by and met with the CDC Division of Healthcare Quality & Promotion (DHQP) to present on the mounting data supporting the need for and efficacy of touch-free aseptic barriers for stethoscope hygiene. During this meeting, AseptiScope's Chief Medical Officer, W. Frank Peacock, MD, presented a review of the clinical evidence.

Discussion on Stethoscope Hygiene Led By:

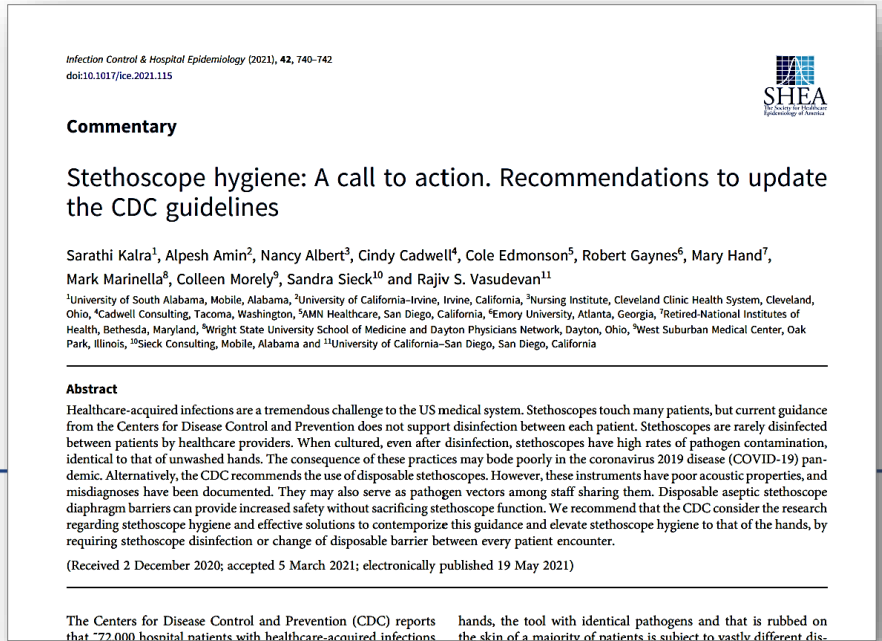
W. Frank Peacock, MD, FACEP, FACC

AseptiScope Chief Medical Officer
Professor, Research Director & Vice Chair for Research,
Department of Emergency Medicine at Baylor College of Medicine

Cliff McDonald, MD

Associate Director for Science
CDC Division of Healthcare Quality & Promotion (DHQP)

CDC Shares Key Publication With AseptiScope:



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SHEA

Commentary

Stethoscope hygiene: A call to action. Recommendations to update the CDC guidelines

Sarathi Kalra[1], Alpesh Amin[2], Nancy Albert[3], Cindy Cadwell[4], Cole Edmonson[5], Robert Gaynes[6], Mary Hand[7], Mark Marinella[8], Colleen Morely[9], Sandra Sieck[10] and Rajiv S. Vasudevan[11]

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Abstract

Healthcare-acquired infections are a tremendous challenge to the US medical system. Stethoscopes touch many patients, but current guidance from the Centers for Disease Control and Prevention does not support disinfection between each patient. Stethoscopes are rarely disinfected between patients by healthcare providers. When cultured, even after disinfection, stethoscopes have high rates of pathogen contamination, identical to that of unwashed hands. The consequence of these practices may bode poorly in the coronavirus 2019 disease (COVID-19) pandemic. Alternatively, the CDC recommends the use of disposable stethoscopes. However, these instruments have poor acoustic properties, and misdiagnoses have been documented. They may also serve as pathogen vectors among staff sharing them. Disposable aseptic stethoscope diaphragm barriers can provide increased safety without sacrificing stethoscope function. We recommend that the CDC consider the research regarding stethoscope hygiene and effective solutions to contemporize this guidance and elevate stethoscope hygiene to that of the hands, by requiring stethoscope disinfection or change of disposable barrier between every patient encounter.

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The Centers for Disease Control and Prevention (CDC) reports that ~72,000 hospital patients with healthcare-acquired infections

hands, the tool with identical pathogens and that is rubbed on the skin of a majority of patients is subject to vastly different dis-

Experts Call on the CDC to Issue **Stethoscope Hygiene Guidelines**

Guidelines and Recommendations

The published literature has matured in advance of new guidelines that will recognize the criticality of the stethoscope vector and elevated hygiene standards. Similar to advances in all technology, the literature regarding the stethoscope as causal in the transmission of iatrogenic infection has markedly elevated in the last decade.

In May of 2021, a "CDC Call to Action" was issued by a working group team of experts in the field, ranging from investigators publishing in this area decades ago,[53] to the expert who coined the term, "The Clinician's Third Hand," [2] to the President of the Heart Failure Society of America and associate Chief Nursing Officer of the Cleveland Clinic, Nancy Albert.[12]

> "We recommend... stethoscope disinfection or the use of disposable barriers should be required between every patient encounter."[55]

This team of experts distilled the most critical data into a statement of need. An evidence-based and well-constructed call-to-action to the CDC for stethoscope hygiene guidelines to be elevated to the level of hand hygiene was published in the SHEA Infection Control & Hospital Epidemiology peer-reviewed journal.[54]

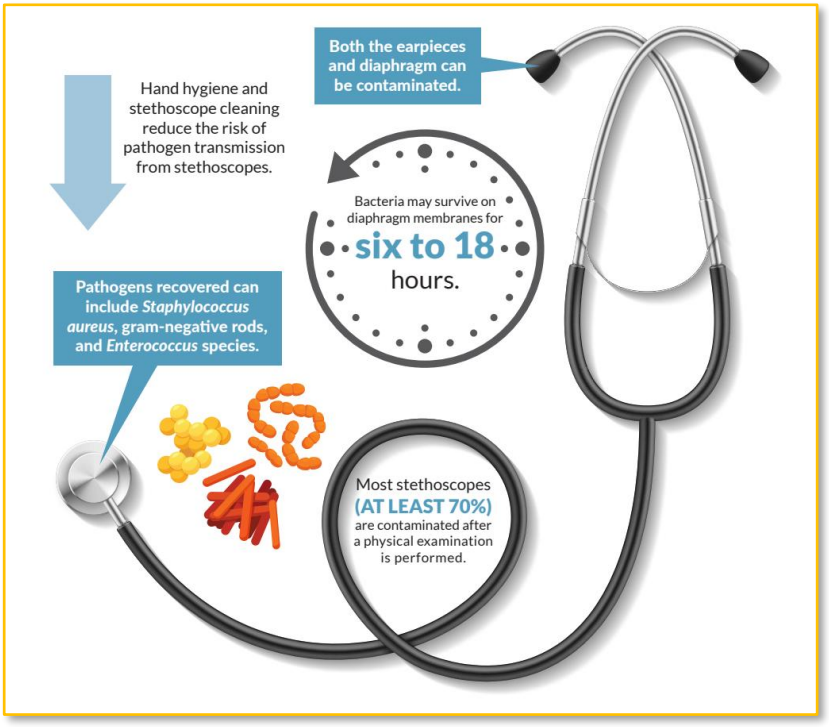
A specific reference to The DiskCover System is made in this publication. It references study data confirming its superiority for infection control and workflow compatibility. The group points to the fact that the CDC defines the stethoscope as a noncritical surface and states that weekly disinfection with alcohol is acceptable unless it is visibly soiled.[55]Although this would never be acceptable for the hands, the tool with identical pathogens and that is rubbed on the skin of a majority of patients is subject to vastly different disinfection recommendations than hands.

The differences in the recommendations between the hands and the stethoscope should be addressed, especially now that the possibility of stethoscope-related coronavirus disease 2019 (COVID-19) transmission must be considered.[54]

Nursing Groups Are Leading

Stethoscope Hygiene Guidelines

Association of periOperative Registered Nurses (AORN) Guidelines



In 2020, the Association of periOperative Registered Nurses (AORN) recognized the need for improved stethoscope hygiene by incorporating guidelines on disinfection practices in their evidence-based *Guideline for Surgical Attire*.

These guidelines emphasize that stethoscopes, which come into direct contact with patients' skin, are a potential mechanism for transmission of pathogens between patients and clinicians alike. They recommend that stethoscope hygiene be conducted before and after every patient encounter to prevent the transmission of pathogens.

Hospitals following AORN guidelines ensure compliance with best practices in infection prevention. By adopting The DiskCover System, facilities can enhance adherence to these standards while improving efficiency in high-touch environments. The DiskCover System standardizes stethoscope hygiene, overcoming the variability in manual cleaning compliance, and supports evidence-based infection prevention protocols like AORN's.

Stethoscope Hygiene Between Patients Is Now **Standard of Care**

Other Stethoscope Hygiene Protocols Have Never Worked

Implementing evidence-based policies and protocols effectively can greatly enhance clinical practices and patient outcomes, including the prevention of healthcare-associated infections.[56] The importance of stethoscope hygiene has been well documented. However, disinfecting the stethoscope with alcohol between every patient encounter is untenable. Compliance with such stethoscope disinfection protocols is notably low due to the inconvenience and time required, and even when adhered to, many disinfectants do not eliminate all pathogens found on the stethoscope. This inherent weakness limits the efficacy of such antiquated protocols to between 10% to 50%.[14]

The discretionary use of alcohol alongside The DiskCover System enables the first-ever evidence-based, high compliance Policy & Procedures (P&Ps) specifically designed for stethoscope hygiene, that are compliant with the CDC's proposed 2024 Guideline to Prevent Transmission of Pathogens in Healthcare Settings.[52] With The DiskCover System, new stethoscope hygiene P&Ps will encourage enhanced patient safety, reduce the risk of healthcare-associated infections, and address compliance issues effectively.

Stethoscope Hygiene Experts In **Healthcare Quality, Critical Care & Infection Prevention**

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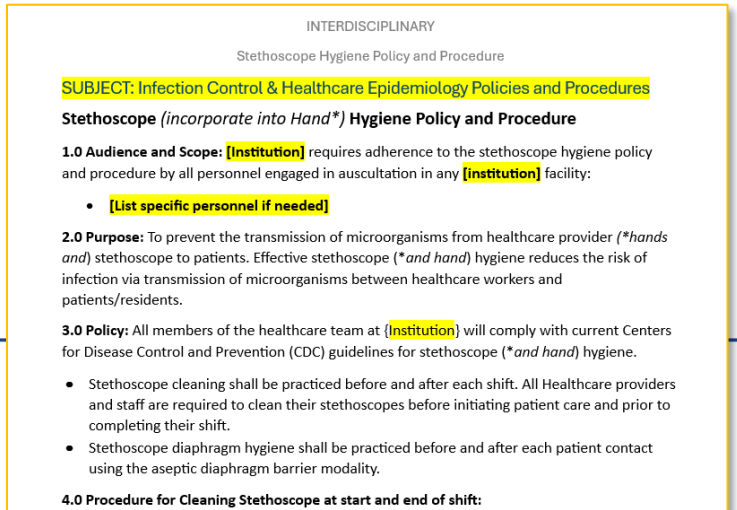
P&P Template is available upon request for integration into your healthcare system.



INTERDISCIPLINARY

Stethoscope Hygiene Policy and Procedure

SUBJECT: Infection Control & Healthcare Epidemiology Policies and Procedures

Stethoscope *(incorporate into Hand*)* **Hygiene Policy and Procedure**

1.0 Audience and Scope: [Institution] requires adherence to the stethoscope hygiene policy and procedure by all personnel engaged in auscultation in any **[institution]** facility:

- **[List specific personnel if needed]**

2.0 Purpose: To prevent the transmission of microorganisms from healthcare provider *(*hands and*) stethoscope to patients. Effective stethoscope (**and hand*) hygiene reduces the risk of infection via transmission of microorganisms between healthcare workers and patients/residents.

3.0 Policy: All members of the healthcare team at {Institution} will comply with current Centers for Disease Control and Prevention (CDC) guidelines for stethoscope (**and hand*) hygiene.

- Stethoscope cleaning shall be practiced before and after each shift. All Healthcare providers and staff are required to clean their stethoscopes before initiating patient care and prior to completing their shift.
- Stethoscope diaphragm hygiene shall be practiced before and after each patient contact using the aseptic diaphragm barrier modality.

4.0 Procedure for Cleaning Stethoscope at start and end of shift:

Human Factors Engineering

Human factors engineering is a discipline focused on examining human capabilities and limitations to design devices and systems that enhance overall performance.[57] Healthcare professionals often face time constraints, making it challenging to adhere to difficult or time-consuming disinfection procedures, such as alcohol disinfection of the stethoscope which takes up to 60 seconds for maximum efficacy.[14]

The DiskCover System was specifically designed with these human factors in mind, offering a standardized approach to stethoscope hygiene. Disk covers offer a 100% effective aseptic barrier that has been demonstrated to block all tested pathogens, with just a 2-second application process. Its simplicity and ease of use promotes a fast integration into regular clinical practice, enabling easier stethoscope hygiene compliance among healthcare staff.

Compliance with HICPAC Framework for Assessment of Products

In Jan. 2020, The CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC) authors published a Special Article in the Annals of Internal Medicine outlining a recommended process for assessing new infection control technology.[58] This features a framework for a stepwise assessment of new innovations for recommendation.[58]

A thorough execution of the steps in the framework when analyzing The DiskCover System explicates its viability as an innovative infection control product and its compatibility and compliance with the standards set by the HICPAC itself. The DiskCover System meets all of the requirements, outlined below, of the HICPIC framework.

The DiskCover System: HICPAC Infection Prevention Product Assessment Algorithm		
A, B	**FDA-cleared**	☑
C	**Class 1 Medical Device**	☑
D	**Value-added clinically relevant human and proxy outcomes**	☑
E	**Indicated use for hygienic patient contact to prevent patient exposure to harmful pathogens and contaminants**	☑
F	**Focused on Infection Prevention**	☑
G	**Mounting efficacy data**	☑
H	**Evidence of safety**	☑
I	**Benefits work to minimize harm**	☑
J	**Superior to current standard of care**	☑
K	**Impact demonstrated when product is used alone**	☑
L, M	**Findings are generalizable across multiple clinical settings and patient categories**	☑
N	**Resource implications clearly outlined**	☑

Entity Benefits

Use of The DiskCover System can benefit multiple stakeholder entities.

Clinicians

The current options for stethoscope hygiene are prohibitive to strong compliance. In lieu of a convenient and efficient means for stethoscope hygiene, clinicians may recognize the need for hygiene, but still fail to achieve it through ABHRs and disposable stethoscopes.[59] The DiskCover System's aseptic stethoscope barriers provide a novel, valuable tool for clinicians that standardizes clinical practices for stethoscope hygiene.

In one study, the DiskCover System was assessed at 7 US centers in an open label registry of clinical users.[20] Results of The DiskCover System End User Acceptance Study were presented in abstract form at the 2022 SHEA annual spring conference.

Of 147 clinical users surveyed, >90% believe The DiskCover System: [21]

- **Is easy to use** with no formal training.
- **Fits or improves their workflow** compared to current options for stethoscope hygiene.
- **Will improve stethoscope hygiene compliance**.
- **Will improve patient safety**.

Patients

When a patient is auscultated by a clinician using a stethoscope protected by a disk cover, they are provided an aseptic surface that completely blocks pathogen transmission from the stethoscope diaphragm. Because of this, use of The DiskCover System reduces pathogen transmission and may result in a reduction in HAI acquired by patients. Unlike cleaning with detergents, a patient can actually see that a clean, single-use disk cover barrier has been placed on the point of contact, reassuring the patient that they are protected. This may serve to improve patient satisfaction, an important element in CMS reimbursement.

Hospitals

In minimizing pathogen transmission from the stethoscope diaphragm to other surfaces, use of The DiskCover System can potentially reduce HAI and patient readmission rates, saving costs and resource utilization and preventing CMS penalties. Because the disk cover barrier is produced in clean room conditions, conditions that are maintained in the Clean Cassette, there is no need for antimicrobials, and thus the system does not contribute to antimicrobial resistance. Further, The DiskCover System has been designed to have a small footprint, allowing for installation close to the point of care to optimize convenience and user compliance.

IV. Materials Management Info

Specifications and Ordering

Specifications				
Item	**Dimensions**	**Weight**	**Operational Temperature**	**Operational Humidity**
DiskCover Dispenser with Clean Cassette	6.08” x 7.98” x 6.30”	2.75 lbs	-20° C ~ 55° C	20% ~ 95%

Ordering Information		
Item	**Part Number**	**List Price**
DiskCover System Starter Kit, includes 1-Dispenser, 1-Clean Cassette, 3-C-cell batteries, 1-wall mount, 4-mounting screws with anchors, 1-informational placard	DSC-KIT	$350.00
DiskCover Dispenser, includes 3-C-cell batteries, 1-wall mount, 4-mounting screws with anchors, 1-informational placard	DSA-1	$199.00
DiskCover Clean Cassette, containing roll of 420 DiskCover Disks	CSA-1	$169.00

Product Indications

The DiskCover System automates the touch-free application of single-use disk covers to stethoscope diaphragms as an aseptic barrier to prevent patient exposure to harmful pathogens and contaminants.

Material Composition

Disk cover material is sourced from 3M. The disk cover material composition consists of a low tack removable acrylic adhesive on the stethoscope diaphragm facing side and a biocompatible polyolefin film backing material on the patient facing side (biocompatibility data on file).

Cleanroom Manufacturing

The DiskCover System Clean Cassettes are manufactured in a cleanroom environment to ensure the integrity of the system's capabilities of providing aseptic disk cover barriers for stethoscope diaphragms.

Manufacturing license and cleanroom registrations are available upon request.

V. Enabling Systems

Purchasing and Customer Support

E-commerce Storefront
Purchasers may order The DiskCover System Starter Kits, Dispensers and Clean Cassettes electronically at list price on AseptiScope's E-commerce storefront.

Quotes & Purchase Orders
Purchasers may submit a request for a quote to orders@aseptiscope.com. Special pricing may be offered depending on volume of purchase and size of institution. Upon customer quote approval, the customer may then submit a purchase order.

Manus Medical & Federal ECAT
Contract #: ECAT SPE2DE20D0014 **| Catalog:** 3263
For federal institutions including Veterans Affairs (VA) Health Care and Federally Recognized Tribes, AseptiScope is proud to be partnered with Manus Medical, a service-disabled veteran-owned small business (SDVOSB), to have The DiskCover System listed on the Federal Electronic Catalog (ECAT) for purchasing.

FDA Unique Device Identifier (UDI) Compliance
All part numbers associated with The DiskCover System are UDI compliant. This allows for improved visibility in the supply chain.

Return Merchandise Authorization (RMA) Procedure
AseptiScope grants RMAs for out-of-box failures, such as failure of the product to function due to damage from transport or manufacture. AseptiScope will initiate case-by-case RMA Exchanges and RMA Refunds depending on the nature of the failure.

Submit RMA requests to orders@aseptiscope.com. Any request for return of products must specify the reason for return, the original order number, quantity, lot number, and invoice number with date. Authorized returned products must be returned to AseptiScope in their original packages, packed appropriately for shipping, and not have been used.

Appropriate RMA Exchange (new product sent for replacement) will be carried out upon authorization of return. RMA Refund (Return Credit Memo) will be carried out upon receipt of the returned product(s).

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